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### Telehealth-Based Gay-Affirmative Cognitive Behavioral Therapy for Young Gay and Bisexual Men in the Rural South

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TELEHEALTH-BASED GAY-AFFIRMATIVE COGNITIVE BEHAVIORAL  
THERAPY FOR YOUNG GAY AND BISEXUAL MEN IN THE RURAL SOUTH

A Thesis Presented to  
The Faculty of The School of Medicine  
Yale University

In Candidacy for the Degree of  
Master of Medical Science

May 2018

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## Abstract

Young rural gay and bisexual men suffer a disproportionate burden of psychiatric disorders compared to their urban and heterosexual counterparts because of the increased stigma-related stressors they face. Co-occurring mental and behavioral health problems often affect them, including depression and substance use disorders. In two randomized controlled trials, a gay-affirmative cognitive behavioral therapy called *Effective Skills to Empower Effective Men* significantly decreased alcohol use, and improved mental health outcomes among urban gay and bisexual men by targeting stigma-related stress responses. However, the intervention's efficacy has not been studied among rural populations. In a randomized controlled trial, we propose to deliver this intervention via telehealth to young gay and bisexual men with co-occurring mental and behavioral health problems in rural areas of the South. A successful ESTEEM trial among rural southern gay and bisexual men could address unmet mental health needs in other rural regions.

## Figures

1. Figure 1: Organizer for various components of stigma, minority stressors, minority and universal stress processes, and syndemic psychosocial outcomes. Adapted from Pachankis et al., 2015

## Chapter 1 – Introduction

### I. Background

Young gay and bisexual men (GBM) experience a higher burden of mental health conditions, including depression, anxiety, and substance use disorders compared to their heterosexual counterparts.<sup>10,4</sup> Other health-risk behaviors prevalent among GBM compound these mental health problems, including alcohol use, sexual compulsivity, and condomless anal sex. Taken together, these mental and behavioral health conditions constitute a group of synergistic comorbidities that undermines GBM's mental and physical health.<sup>17,15,18,20</sup> Previous research into the origins of these mental and behavioral health disparities conceptualizes them in terms of minority stress theory, which holds that the stress of being a sexual minority (or a member of any minority group) accrues over time and results in long term mental and physical health deficits.<sup>13,14</sup>

Central to the conceptualization of how minority stress affects GBM and other sexual minorities is the distinction between distal and proximal minority stressors.<sup>13,14</sup> A distal minority stressor is external to the individual, and includes experiences such as rejection, discrimination, and anti-sexual minority violence. Proximal minority stress processes are internal and believed to occur secondary to distal stressors.<sup>13,14</sup> Examples of proximal minority stressors include identity concealment, hypervigilance or sensitivity to rejection, and internalized homophobia. The accumulation of distal and proximal stressors over time leads to high levels of chronic stress, which in turn can result in worse health outcomes.<sup>13,14</sup> Subsequent research that builds on this framework of minority stress theory focuses on the mediating effect of universal psychological processes, such as

rumination, social isolation, and hopelessness, that are theorized to combine with group-specific minority stressors to engender psychopathology in sexual minorities.

Another body of psychological research that draws from and contributes to minority stress theory is the concept of stigma. Stigma is defined by Link and Phelan as the “co-occurrence of labeling, stereotyping, separation, status loss, and discrimination in a context in which power is exercised”.<sup>10,7</sup> Stigma itself is a socially-mediated, supra-individual factor whose deleterious effects on mental and physical health are well documented in the literature.<sup>7</sup> Structural stigma, in particular, has recently been shown to be a risk factor for worse physical and mental health outcomes among sexual minorities.<sup>7</sup> Structural stigma describes the societal structures and institutions that deny sexual minorities the same rights, privileges, and opportunities given to heterosexuals, such as workplace protections, marriage rights, and legal protections against violence.<sup>17</sup> Structural stigma perpetuates a social environment that enables discrimination within larger social structures such as families, religious communities, schools, workplaces, and everyday social interactions.<sup>17</sup> The result of these compounded discriminatory experiences toward a stigmatized identity is increased exposure to group-specific distal minority stressors, which in turn increases the proximal psychological stress responses. These stress responses result in higher mental disorder burden among sexual minorities.

Research into structural stigma shows that geographic location, community-level attitudes, and governmental policies all constitute important determinants of sexual minority mental health. Hatzenbuehler and Link describe this interplay between governmental policies and structural stigma as the “societal-level conditions, cultural norms, and institutional policies that constrain the opportunities, resources, and well-



being of the stigmatized”.<sup>6,7</sup> In terms of social policies, studies have shown a strong association between governmental policy and mental health outcomes for sexual minorities. In a study that compared states with legal non-discrimination and hate-crime protections for gay men and lesbians with individual-level data on sexual orientation and psychiatric disorders from a nationally representative sample, the prevalence of psychiatric disorders was significantly higher among gay men and lesbians who lived in states with no protections versus sexual minority adults who live in states with legal protections.<sup>7</sup> This data highlights the negative impact that structural stigma has on sexual minorities.

Legal policies and laws can be understood as a reflection of community-level attitudes. Community level attitudes, in turn, are the context in which interpersonal stigma manifests. Interpersonal stigma describes prejudicial or discriminatory acts or speech directed from one individual to another.<sup>16</sup> A 2012 metanalysis of victimization among lesbian, gay, and bisexual (LGB) individuals showed that verbal and physical harassment are the most common forms of interpersonal stigma, but other forms of victimization remain prevalent.<sup>8,16</sup> Moreover, the positive associations between discriminatory experiences and worse mental and physical health outcomes among LGB individuals is well documented in the literature.<sup>12</sup>

The concepts of minority stress, structural stigma, and interpersonal stigma as they relate to gay and bisexual men’s mental and physical health serve as a conceptual basis from which to understand how rurality might operate as an important determinant of GBM’s health. Rurality, as a concept, may seem obvious in that it is typically defined in contradistinction to urban spaces, but Boso notes that rurality as a concept is

contextually dependent and is harder to define than it may seem.<sup>1</sup> For example, a rural fishing community in New England would differ significantly from a farming community in the Midwest, or a Native American reservation in the Southwest. Each is undoubtedly rural while being in many ways distinct. To define what it means to be rural, one may imagine sparsely populated areas far from a metropolitan area, with small, homogenous communities that interact in the relatively few public gathering places that their communities offer (i.e., churches, schools, and markets). Such a conception, while true to some extent, obscures a broader sense of rurality, which, Boso argues, can “be a place, a culture, a way of life, and even an identity”.<sup>1</sup> Despite the variety of places, cultures, and spaces that can be considered rural, it is possible to discern commonalities in the varied experiences of rural sexual minorities, particularly as they relate to interpersonal and structural stigma.

Sexual minorities who live in rural spaces often confront a range of difficulties based in interpersonal and structural stigma that undermine their ability to both have their own rural identity and have that identity be accepted by their communities. A fundamental experience of life in rural communities that can negatively affect sexual minorities is what Boso describes as the “high density of acquaintanceship,” meaning that the relative scarcity of people in rural communities necessitates greater social emphasis on casual interactions, which can strengthen the impact of prejudicial experiences.<sup>1</sup> Another factor that shapes rural community-level attitudes is the importance of presenting an identity that is congruent with the larger group, based on the “solidarity expressed through blending in and not setting oneself apart”.<sup>1,5</sup> Moreover, social norms in rural communities tend to be conservative, and place value on religious life and

institutions.<sup>1</sup> This emphasis on conformity to traditional social and religious norms can isolate rural sexual minorities and deprive them of the acceptance and support of friends, family, and neighbors.<sup>1</sup> These experiences of structural stigma, isolation, and discrimination all serve to undermine the mental health of sexual minorities living in rural areas.<sup>3</sup>

As mentioned previously, geographic location plays a significant role in experienced structural and interpersonal stigma in that geographic location determines the particular cultural and historical norms that are unique to regions and localities. The South is a region of the United States (US) that stretches from Texas to Maryland, including all the states in the southeastern portion of the US. Many southern states count among the most rural states by percentage of population.<sup>2</sup> The South is widely considered to be one of the most religiously and culturally conservative regions of the US. Additionally, the South is home to 35% of the lesbian, gay, bisexual and transgender (LGBT) population of the United States, which is the highest percentage of any region.<sup>23</sup> In a nationwide study of rural lesbians, gay men, and bisexuals (LGBs) and their experiences with minority stress, Southern LGBs reported the highest levels of recent and lifetime experiences of discrimination and reported feeling the least connection to and LGBT community.<sup>21</sup> These factors make the South amenable to studying interventions that seek to increase resilience and coping skills among GBM in order to the mitigate the harmful effects of stigma and minority stress experiences.

The cultural and social conservatism in the South also translates to the policy arena, with southerners (including sexual minorities) facing some of the highest poverty rates, least workplace protections, and lowest rates of health insurance coverage in the

US.<sup>23</sup> The South also leads the nation in new HIV infections among men who have sex with men (MSM).<sup>23</sup> These new HIV infections add to the stigma that GBM and other men who have sex with men already face by navigating a stigmatized identity or sexual behavior in a rural setting. Southern states in general provide less funding for social services, including public mental health care services, with rural areas being particularly underserved.<sup>19</sup>

Alabama is a rural southern state with some of the fewest legal protections for sexual minorities and highest rates of sexual minorities living in poverty and lacking health insurance relative to other states.<sup>25</sup> Alabama is home to at least 104,000 LGBT individuals<sup>25</sup> Alabama has at least 6,600 same sex households, many of which exist in the state's rural counties.<sup>25</sup> The LGBT population in Alabama is also racially and ethnically diverse, with African Americans comprising 31% and Latinos comprising 7% of the total population.<sup>25</sup> Alabama's central geographic location in the Deep South, as well as its significant rural GBM population, cultural conservatism, racial diversity, and high need for mental health care services mark it as an area that could benefit from a telehealth-based mental health intervention targeted to GBM. Rural regions of geographically neighboring states, including eastern Mississippi, western Georgia, southern Tennessee, and northern Florida, share similarities in terms of racial, economic, and cultural factors that affect sexual minorities.<sup>23</sup> Thus, basing an telehealth intervention in Alabama with outreach to neighboring states would allow researchers to recruit from an area of the country with the highest need for GBM-specific mental health services.

## II. Statement of the Problem

Young GBM living in rural communities in the US experience disproportionate mental health burden as well as increased minority stressors compared to urban gay men.<sup>22</sup> The relative lack of mental health resources in rural communities compared to urban areas contributes to this problem.<sup>11</sup> Psychiatric disorders, including depression and anxiety, are often comorbid with health-risk behaviors such as alcohol use, condomless anal sex, and sexual compulsivity.<sup>17</sup> These clusters of mental and behavioral health problems constitute a synergistic comorbidity, or a syndemic, surrounding GBM.

The syndemic nature of the mental health problems faced by GBM present challenges in effectively treating only one mental health or behavioral condition without treating others.<sup>24</sup> A transdiagnostic (i.e., addresses mental health issues across a range of diagnoses), GBM-specific cognitive behavioral therapy (CBT) intervention that is adapted from the *Unified Protocol for the Transdiagnostic Treatment of Emotional Disorders*, has been shown in two separate randomized controlled trials (RCT) to produce statistically significant decreases in depressive symptoms, anxiety, and sexual compulsivity among GBM.<sup>24,17</sup> Additionally, the two trials showed marginally significant decreases in alcohol consumption and substance use.<sup>24,17</sup> The researchers who developed this modified transdiagnostic CBT intervention call it the *Effective Skills to Empower Effective Men* (ESTEEM). The ESTEEM model works by helping participants identify the connections between minority stress and stress-sensitive disorders. Additionally, ESTEEM targets maladaptive cognitive, affective, and behavioral avoidance patterns that derive from minority stress experiences; it also enhances emotion regulation abilities and improves motivation and self-efficacy for enacting behavior change.<sup>17</sup>

The efficacy results of ESTEEM, while promising, have only been studied in urban GBM. This presents a notable gap in the literature of using GBM or LGBT-specific transdiagnostic therapies to treat mental and behavioral health disorders. Considering the high psychological disease burden among rural GBM, implementing ESTEEM to serve a rural GBM population would address a strong need, perhaps even greater than the need among urban GBM. In order to overcome the relative lack of mental health resources in rural communities, the ESTEEM intervention will be delivered via telehealth by trained mental health professionals. The efficacy of non-GBM-specific CBT delivered via telemedicine is well documented and has been found to be equally effective to in-person CBT.<sup>26</sup> The proposed study will address the research question of whether or not a GBM-specific modified form of transdiagnostic CBT is more efficacious than a non-GBM-modified transdiagnostic CBT program at reducing depressive symptoms, as well as other key mental and behavioral health measures, in a rural, southern GBM population.

### III. Goals and Objectives

The primary goal of the study is to test the efficacy of a telehealth-delivered transdiagnostic CBT intervention modified to target GBM-specific minority stress processes, called ESTEEM, among young GBM in rural Alabama, eastern Mississippi, western Georgia, southern Tennessee, and northern Florida to improve mental health outcomes including depression, anxiety, and co-occurring behavioral health problems, such as substance use and sexual risk behavior. If the efficacy of ESTEEM is demonstrated when compared against the *Unified Protocol for Transdiagnostic Treatment of Emotional Disorders* (a non-GBM-specific transdiagnostic CBT), it will

strengthen the evidence for the development of more LGBT-specific mental health therapies. Efficacy of the ESTEEM intervention delivered via a telehealth platform would also further expand the options in terms of populations who can benefit from ESTEEM and similar types of transdiagnostic therapies, such as the Unified Protocol.

#### IV. Hypothesis

We hypothesize that a telehealth-delivered transdiagnostic cognitive behavioral therapy (CBT) intervention designed to reduce minority stress among young, rural gay and bisexual men will yield significantly greater reductions in our primary outcome – depressive symptoms as measured by mean change from baseline of the Overall Depression Severity & Impairment Scale (ODSIS) scale – compared to a telehealth-delivered, non-GBM-specific Unified Protocol.

#### V. Definitions

- *Transdiagnostic* – describes the fact that a proposed intervention addresses symptoms related to multiple mental or behavioral health disorders, as opposed to an intervention aimed at one disorder or one symptom.
- *Depressive symptoms* – defined as sleep disturbances, changes in interest, changes in concentration, changes in appetite, psychomotor changes, or suicidal ideation.

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## Chapter 2 – Literature Review

### I. Introduction

A comprehensive review of literature relevant to the present study was conducted between August 2017 and April 2018. The purpose of this literature review is to provide a summary of the scholarly literature related to mental and behavioral health issues among GBM and other sexual minorities, transdiagnostic cognitive behavioral therapies, the state of LGB-focused mental health interventions, as well as greater context around mental health among sexual minorities in the rural South. Studies published subsequent to April 2018 are not included in this review. Primary search databases include Ovid MEDLINE, EMBASE, psychINFO and the Cochrane Library. Several key umbrella search terms were used, including “sexual minority”, “LGBT”, “gay”, “bisexual”, “MSM”, “rural”, “mental health”, “depression”, “anxiety”, “substance use”, and “psychiatric disorder”. Various combinations of these terms were used to maximize search results. References were not filtered for language or age. References cited in selected articles were further examined to ensure a comprehensive review.

### II. Minority Stress Theory and Sexual Minority Health

#### *2.1 Minority Stress Theory and its Historical Antecedents*

Minority stress theory draws on a tradition of psychological and social science research which argues that health disparities present in minority populations, whether religious, ethnic, racial or sexual, have their basis in stress derived from adverse social situations. One of the earlier articulations of this idea was the so-called ‘social causation

hypothesis' found in Dohrenwend's 1966 *Social Status and Psychological Disorder: An Issue of Substance and an Issue of Method*, which argued that poor mental health outcomes were due to low social status.<sup>27</sup> Subsequent empirical research supported the relationship between social stressors (e.g., low status) and psychopathology, allowing Dohrenwend to develop a framework to conceptualize social stress processes within the individual context as well as the broader social environment.<sup>28,14</sup> Meyer's analysis expands on Dohrenwend's social stress framework by focusing on minority stress processes and their specific effects on sexual minorities.

Meyer's seminal meta-analysis on minority stress theory, *Prejudice, Social Stress, and Mental Health in Lesbian, Gay, and Bisexual Populations: Conceptual Issues and Research Evidence*, furthers the social causation hypothesis while simultaneously asserting that social problems do not lead directly to mental health problems for minority individuals. Instead, Meyer argues that difficult social situations lead to minority stress, which accrues over time and results in worse physical and mental health outcomes.<sup>13,14</sup> Minority stress theory distinguishes between distal and proximal stress processes generally, but Meyer's analysis focuses discussion of these processes in the contexts of sexual minorities. Distal minority stress processes that are external to the individual, such as experiences of anti-LGBT discrimination, prejudice, or violence.<sup>13,14</sup> Proximal minority stress processes are internal to the individual and are often secondary to the distal stressors; proximal stress process include various coping mechanisms such as vigilance, concealment of identity, and internalized homophobia.<sup>13,14</sup>

## *2.2 Minority Stress Theory and Stigma*

Minority stress theory argues that psychological problems are not inherent to the sexual minority individual, but are the result of stigma directed toward them by people and institutions.<sup>13,16</sup> Stigma is a broad term that describes various forms of prejudicial treatment towards individuals who are considered to be unworthy of equal respect. Stigma that originates from other individuals is termed interpersonal stigma; whereas, structural stigma describes the stigma that originates from institutions.

Minority stress theory posits that both interpersonal stigma and structural stigma negatively affect GBM through several psychosocial stress processes, some of which are specific to sexual minorities.<sup>13</sup> Such GBM-specific psychosocial stress processes include stigma-based rejection sensitivity, internalized homophobia, and concealment.<sup>13,30,31</sup> There are other cognitive, affective, and behavioral processes that are related to GBM's exposure to stigma that are not specific to being a sexual minority, but that are elevated among sexual minorities compared to heterosexuals. These universal stress processes include hopelessness, rumination, and social isolation; these same universal stress processes also serve as risk factors for mental health problems.<sup>6</sup>

### III. Review of the Sexual Minority Mental and Behavioral Health Literature

#### *3.1 Mental, Behavioral and Physical Health Challenges Facing Sexual Minorities*

*Sexual minority* is a term used to describe people whose sexual identity, orientation or practices differ from the majority of society. This grouping includes people who identify as gay, lesbian, bisexual, and/or those who engage in same-sexual behaviors. Sexual minorities represent a diverse population in terms of racial, ethnic, socio-economic status, and other demographic factors. This diversity also extends to their

experiences with minority stress and their individual coping resources.<sup>16</sup> Despite such diversity, stigma represents a persistent commonality among many sexual minorities' experiences, due to their stigmatized sexual identities.<sup>16</sup> Sexual minorities have a long history of stigmatization at the hands of government policies, religious censure, and societal norms that value heterosexuality to the exclusion of same-sex love, desires, and relationships. The vestiges of this history persist today in various forms of structural and interpersonal stigmatization. For example, there is no US federal law, and few state laws, that protect sexual minority individuals from being fired or discriminated against on the basis of their sexual orientation.<sup>16</sup> Moreover, as recently as 2014, a Pew Research Center national public opinion poll showed that a significant portion of the American public does not approve of sexual minority identities.<sup>32,16</sup> While significant anti-LGBT sentiments remain in society at large, profound shifts have taken place in the public's attitude toward sexual minorities' rights to pursue legal marriage, to serve openly in the military, and otherwise exist freely in society.<sup>16</sup>

Historically, medicine as an institution was a major contributor to the stigmatization of sexual minorities. Psychiatry categorized homosexuality as a mental illness in the *Diagnostic and Statistical Manual of Mental Disorders* for decades, before it removing it in 1973.<sup>33</sup> By pathologizing and attempting to "cure" homosexuals, psychiatry and the medical establishment equated departures from heterosexuality with psychological deficits and the stigma that attends mental illness.<sup>33</sup> Attempts to "treat" homosexuality were often emotionally, and sometimes physically, abusive.<sup>16,35</sup> Even today, so-called conversion therapies exist, but they are no longer endorsed by the medical establishment and are known to be harmful.<sup>16,35,36</sup> While many overt forms of

sexual minority stigmatization and mistreatment in medicine have abated in the last 40 years, stigma persists in various forms. Significant inequities in health insurance coverage, discrimination from providers, and lack of physician training about sexual minority health concerns all remain significant barriers to care.<sup>16,37</sup> Moreover, failure to routinely assess sexual orientation in medical settings and national health surveys deprives researchers of raw data necessary to study trends in mental and physical health for LGB patients.

It is against this historical backdrop that one must view the body of research into sexual minorities' mental and physical health outcomes. Until the 1980s, there was very little research that specifically assessed data related to sexual minorities. Research abruptly increased in the 1980s because public health officials realized that men who have sex with men (MSM) were disproportionately affected by the HIV/AIDS epidemic. This shift in public health research priorities to include MSM gradually expanded to include other sexual minorities over the years. While current data on sexual minorities is more robust than before, research-funding priorities for sexual minorities still lags behind other minority populations; and much of the funding that does exist is devoted to studying HIV among MSM.<sup>16</sup>

As more population-based studies have assessed the health status of sexual minorities, researchers now have significant data on population prevalence of the mental and physical health disorder burden among this group. Overall, evidence suggests that sexual minorities experience worse physical health outcomes, significantly higher rates of certain types of diseases, and more disability compared to the heterosexual population.<sup>38,39,16</sup> In terms of the specific health conditions faced by sexual minorities,

sexual minority women are at higher risk for breast cancer, obesity, and cardiovascular disease, compared with heterosexual women.<sup>40,41</sup> Sexual minority men and women are both more likely to develop asthma and type 2 diabetes mellitus.<sup>40,42,43</sup> Additionally, sexual minority men are at higher risk for HIV infection, anal cancer, lymphoma, and headaches compared to heterosexual men.<sup>38,44,16</sup> Though several potential biological explanations exist for why these specific disease processes affect sexual minorities more so than their heterosexual counterparts, the potential links between stigma, mental health, and these physical health disparities is an area of ongoing research.<sup>16</sup>

Mental health is another area in which sexual minorities suffer worse outcomes than their heterosexual counterparts. Research has shown clear evidence that sexual minority individuals are significantly more likely than heterosexuals to experience mood, anxiety, and substance use disorders.<sup>13,45</sup> This association between mental health problems and physical health problems is also well documented in the literature.<sup>13,14,46</sup> Mental health disorders are associated with disproportionate engagement in health-risk behaviors (e.g., binge drinking and unprotected sex) among sexual minorities compared to heterosexuals, particularly in younger age groups.<sup>47</sup> The associations between mental health, increased health-risk behaviors, and worse physical health outcomes among sexual minorities necessitate further research into interventions to improve mental, physical and behavioral health outcomes in this population.

### *3.2 Mental and Behavioral-Health Challenges Specific to Gay and Bisexual Men*

Gay and bisexual men are significantly more likely to experience mental health disorders, such as major depressive disorder or anxiety disorders, compared to heterosexuals.<sup>48,49,50,17</sup> This group is even more at risk for mental health problems than

sexual minority females.<sup>49</sup> This gender disparity is thought to be related to greater stigma assigned to male homosexual behavior.<sup>49</sup> A population-based study in the Netherlands highlights the mental health disparities particular to GBM. Researchers found a higher 12-month prevalence of depressive disorders and anxiety disorders compared to heterosexual men.<sup>51</sup> The same study showed that GBM were the most likely to have more than one psychiatric disorder over a 12-month period, compared to either heterosexuals or other sexual minorities.<sup>51</sup>

A growing body of research demonstrates that these mental health problems experienced by GBM are exacerbated by health-risk behaviors, including excessive alcohol use, sexual compulsivity, and condomless anal sex. Together with mental health problems, these health-risk behaviors pose a synergistic comorbidity, or syndemic.<sup>15,24,52,20</sup> In terms of substance use, research has shown higher rates of tobacco, alcohol, and non-medical drug use compared to heterosexuals.<sup>53</sup> The links between elevated rates of substance abuse and experiences of minority stress are also well documented in the literature<sup>16</sup> A prospective study of gay men measuring self-reports of internalized homophobia, discrimination, and rejection sensitivity found positive associations with substance use.<sup>54</sup> Other studies found that structural stigma and minority stress processes explained substance use among sexual minority men.<sup>16,98,99</sup> Taken as a whole, this body of research points to strong associations between stigma, minority stress processes, and substance abuse among GBM other sexual minorities.

A prominent example of how this syndemic relates to structural stigma is the incidence of HIV infection among GBM in the US. In 2016, GBM constituted 67% of all new HIV infections in the US.<sup>55</sup> As such, GBM in the US are over 40 times more likely



to contract HIV than their heterosexual counterparts.<sup>52,16</sup> The primary route of HIV transmission among GBM is anal sex. Significant stigma surrounds anal sex, and this stigma interferes with GBM's access to knowledge and services meant to reduce the risk of HIV and other STI transmission.<sup>16</sup> Moreover, ongoing research into syndemic health risks supports the positive association between psychosocial health risk behaviors (e.g., polysubstance use, high-risk sex, depression) and vulnerability to HIV infection. Stall et al. conducted a study using a probability sample of GBM in four major US cities and found that risk for both HIV infection and sexual risk behaviors (condomless anal sex with partner of unknown or serodiscordant HIV status) increased with each psychosocial health problem a GBM individual endorsed.<sup>20</sup> Mustanski et al. corroborated this finding in a study using a sample of young GBM ages 16 to 24. In this study each psychosocial health problem endorsed by a young GBM significantly increased the odds of unprotected anal intercourse, multiple sex partners, and HIV infection.<sup>15</sup> In the context of heightened HIV risk and substantial mental health burden, the syndemic nature of the health threats to GBM necessitate research focused on interventions that can improve health outcomes for this vulnerable population.

Geographic location also plays a mediating role in GBM's access to HIV-preventive knowledge and treatment. For example, in geographic areas with more structural stigma toward sexual minorities (e.g., lack of recognition of same-sex couples and lack of workplace nondiscrimination policies), sexual minority men are less likely to report accurate HIV transmission knowledge as well as correct and consistent condom usage.<sup>16,56,17</sup> GBM are also less likely to receive HIV preventative health services, including sexually transmitted infection (STI) screening and use of HIV prophylactic

medication.<sup>16,56,17</sup> This interplay between stigma, sexual risk behaviors, and worse mental and sexual health outcomes for GBM underscore the importance of interventions that address the effects of stigma.

### *3.3 GBM-Specific Minority Stress Processes*

Rejection sensitivity, alternately termed rejection hypervigilance, describes a maladaptive coping strategy that sexual minorities adopt to deal with interpersonal stigma. Meyer notes that sexual minorities who experience anti-LGBT prejudice, or fear such experiences, come to expect negative regard from the dominant culture.<sup>14</sup> To combat or avoid that negative regard, sexual minority individuals practice vigilance when interacting with members of the majority culture. This vigilance is necessarily chronic in nature, and is described by Crocker and Major as a “need to be constantly ‘on guard’...alert, or mindful of the possibility that the other person is prejudiced” (p. 251).<sup>14</sup> Rejection hypervigilance is also associated with physiological symptoms such as physical pain, dysregulated inflammatory activity, and hormonal dysregulation.<sup>16</sup> Sexual minority individuals may be more likely experience to the harmful psychologic and physiologic effects of rejection sensitivity.<sup>57</sup> For example, Cole et al. showed that HIV-positive men who reported rejection hypervigilance experienced faster disease progression and higher overall mortality compared to those who were less vigilant.<sup>58</sup>

Fear of stigma can motivate sexual minorities to conceal their identities in order to avoid future victimization.<sup>16,59</sup> Concealment can be a useful coping strategy in the short term to help minorities cope with difficult or dangerous situations, but it is associated with worse psychological outcomes in the long term.<sup>60,61,16</sup> Meyer cites several

studies that describe the negative psychological impact of concealment, particularly among young and adolescent sexual minorities.<sup>14</sup> Hetrick and Martin described “learning to hide” as the most common coping strategy of sexual minority adolescents, stating that:

“individuals in such a position must constantly monitor their behavior in all circumstances: How one dresses, speaks, walks, and talks become constant sources of possible discovery. One must limit one’s friends, one’s interests, and one’s expression, for fear that one might be found guilty by association....”  
(p. 35-36).<sup>62,14</sup>

Some adult sexual minorities may also feel the need to conceal their identity, and therefore suffer from the negative effects of concealment. Smart and Wegner describe the “hidden cost” of concealing one’s stigmatized identity in terms of the cognitive burden that results from a preoccupation with hiding.<sup>63,14</sup> GBM living with HIV are a population for whom the “hidden cost” of concealment is well documented. Research on GBM living with HIV has consistently shown links between concealment of sexual orientation or identity with physical health problems, including diagnoses of cancer, increased susceptibility to infectious diseases, rapid disease progression, dysregulated immune function, and mortality.<sup>58,64,65</sup>

Internalized homophobia is among the most severe consequences of socially-mediated stigma. Meyer and Dean define internalized homophobia as “the gay person’s direction of negative social attitudes toward the self, leading to a devaluation of the self and resultant internal conflicts and poor self-regard” (p. 161).<sup>29,14</sup> Negative self-regard secondary to internalized homophobia has been associated with poor health outcomes among sexual minority individuals.<sup>30</sup> In Denton’s prospective study, which utilized one

large convenience sample, the results indicated that higher self-reported internalized homophobia, along with higher expectations of rejection and victimization, predicted greater reported physical symptom severity among sexual minorities.<sup>67,16</sup> A prospective study of gay men by Hatzenbeuhler et al. showed that self-reported internalized homophobia was associated with substance use.<sup>54</sup> Other studies focusing on the negative mental and physical health outcomes related to internalized homophobia have observed an increased prevalence of depressive symptoms, anxiety symptoms, suicidal ideation, substance use disorders, as well as HIV-risk taking behaviors.<sup>14,67,68</sup> Thus, internalized homophobia is a wide-ranging problem among the GBM community that accounts for significant mental and physical health burden. Moreover, internalized homophobia constitutes an important target for clinical psychological interventions and further research.

### *3.5 Stigma and Universal Stress Processes*

<i>Structural and Interpersonal Minority Stressors</i>	<i>Minority Stress Processes and Universal Stress Processes</i>	<i>Psychosocial Syndemic Outcomes</i>
Structural Stigma	<u>Minority Stress Processes</u>	Depression
Family Rejection	Rejection Sensitivity	Anxiety
Peer Rejection	Internalized Homophobia	Substance Use
Religious Exclusion	Concealment	Sexual Compulsivity
Workplace Discrimination	<u>Universal Stress Processes</u>	Condomless Anal Sex
Everyday Discrimination	Rumination	
	Emotional dysregulation	

	Loneliness	
	Unassertiveness	

Figure 1: Organizer for various components of stigma, minority stressors, minority and universal stress processes, and syndemic psychosocial outcomes. Adapted from Pachankis et al., 2015.

Rumination is a universal stress process that particularly affects GBM and other sexual minorities. Rumination is a maladaptive emotional regulation strategy that involves a persistent and repeated focus on stressful experiences and their consequences.<sup>16</sup> Multiple studies have shown that rumination is more prevalent among sexual minority adults and adolescents compared to their heterosexual counterparts; these ruminations are also associated with minority stress processes.<sup>54,69</sup> In an experience-sampling study, Hatzenbuehler et al. showed that sexual minority young adults were more likely to ruminate on days when they were subject to anti-gay stigma, and that these ruminations were positively associated with physiological distress.<sup>69</sup> Thus, rumination represents a universal stress process that is related to, and additive upon, minority stress experiences that affect GBM. Rumination also constitutes a target for interventions to alleviate the mental health burden among GBM.

Loneliness, or lack of social support, is another universal stress process that is compounded by minority stress and affects GBM and other sexual minorities disproportionately. Due to frequent experiences of rejection from friends or family members while coming out, loneliness appears to be particularly common among GBM and other sexual minorities.<sup>70,16</sup> The harmful effects of loneliness in terms of morbidity and mortality are well documented among the general population, as well as sexual

minorities.<sup>71</sup> Loneliness has profound effects on neurodevelopment in humans and other social animals, and has been linked to cognitive decline, recurrent stroke, elevated blood pressure, and decreased immune function.<sup>71</sup> A meta-analysis of loneliness and social isolation as risk factors for mortality showed that mortality odds increase by 30% among lonely individuals.<sup>72</sup>

Unassertiveness is a universal stress process that also disproportionately affects GBM. Unassertiveness describes the trait of a person who does not assert their needs or wants in a social context in which it would be appropriate to do so (e.g., approaching others or responding to rudeness). Pachankis et al. propose that unassertiveness among GBM may be understood in terms of its relationship to rejection sensitivity.<sup>31</sup> The mechanism proposed to explain the relationship between rejection sensitivity and unassertiveness is the idea that previous rejection (either from parents, other family members, or peers) on the basis of their sexuality causes them to feel unworthy or unable to express themselves, or to otherwise desire to limit their interactions to avoid future rejection. Research on the general population showing the link between unassertiveness and rigid expectations of rejection has existed for decades, underscoring the universality of this process.<sup>31,73</sup> Thus, unassertiveness is another universal process with roots in minority stress that could be targeted by a therapeutic intervention.

Emotional dysregulation describes an emotional response that is poorly understood or controlled by the person in whom it occurs. Emotional dysregulation is a universal stress process that can inhibit a GBM individual's ability to appropriately deal with his emotions. Gratz and Roemer describe six separate dimensions in which emotional dysregulation can occur:

“(a) lack of awareness of emotional responses, (b) lack of clarity of emotional responses, (c) nonacceptance of emotional responses, (d) limited access to emotion regulation strategies perceived as effective, (e) difficulties controlling impulses when experiencing negative emotions, and (f) difficulties engaging in goal-directed behaviors when experiencing negative emotions”  
(p. 52).<sup>74</sup>

Each of these dimensions of emotional regulation are particularly relevant to GBM, because emotional dysregulation a common factor among the maladaptive cognitive, affective, and behavioral responses to minority stress that GBM experience. Moreover, various cognitive behavioral therapies used to treat depression, anxiety, and substance use disorders among GBM are theorized to function by targeting elements of emotional dysregulation.<sup>75</sup>

### *3.6 Stigma, Sexual Minorities, and the Rural South*

Sexual stigma is a form of interpersonal stigma that can lead non-heterosexual individuals to experience internalized homophobia or other types of proximal minority stress responses.<sup>21</sup> The prevalence of sexual stigma in the South derives in part from the social conservatism that is common in rural areas of the South.<sup>76</sup> Johnson and Stokes note that this greater conservatism of Southern communities is partly due to greater prevalence of personal piety (e.g. prayer), and the acceptance of orthodox-fundamentalist religious beliefs, which explicitly condemn homosexuality.<sup>21,76</sup> Particularly in the Deep South, moreover, gender norms are also more likely to be strictly interpreted within traditional roles for men and women.<sup>76,77</sup>

Few studies have directly measured how sexual stigma and other minority stress processes affect GBM living in the rural south. There are a number of studies that explored minority stress processes as they relate to geographic location in general, but results are varied depending on study methodologies. In the literature documenting how minority stress affects rural sexual minorities, qualitative studies overwhelmingly paint rural locales as “bleak and inhospitable social climates” (p.228).<sup>21</sup> These qualitative studies often present rural locations as socially isolating and unwelcoming places to escape from, whereas cities are positioned as bastions of LGBT acceptance and liberalism.<sup>21</sup> For instance, Barton’s study of 46 rural lesbian, gay, and bisexual (LGB) individuals in the “Bible Belt” (a region of the South in which Christian fundamentalism is prevalent) describes painful lives permeated by minority stressors such as isolation, abuse, and internalized homophobia, resulting in depression, fear, and feelings of worthlessness.<sup>78</sup>

Swank et al. note that quantitative studies on minority stress and location offer less consistent results.<sup>21</sup> Some quantitative studies have detected no significant differences in the effects of minority stress in urban versus rural location.<sup>21</sup> For example, Puckett et al. showed no differences in internalized homophobia, social support, or stigma consciousness between rural and urban mothers in a national sample of 414 rural same-sex partnerships.<sup>79</sup> This discrepancy in the qualitative and quantitative literatures was addressed by Swank and colleagues’ 2012 cross-sectional study, which measured minority stress among LGBs in the rural South. Considering the dearth of studies that have addressed this specific relationship between Southern rural location and LGB



stigma, Swank et al. remains the most relevant study of minority stress in this specific population.

The nationally representative sample of LGB men and women used in Swank et al. produced several relevant findings for Southern LGBs. The study assessed felt discrimination, enacted discrimination (both short and long term), and feelings of connectedness to an LGB community. Southern sexual minorities reported higher levels of both recent and lifetime discrimination.<sup>21</sup> They also consistently reported less connection to an LGB community, which is known to have protective coping effects.<sup>21</sup> According to the study's authors: "these findings clearly suggest that the South is a harsher place for sexual minorities than other regions of the United States" (p.237).<sup>21</sup> Other notable findings include more enacted discrimination during their lifetime for rural GBM compared to rural sexual minority women. The study also noted the protective effect of higher income against experiences of felt or long-term discrimination among both rural gay men and lesbians.<sup>21</sup> Thus, Southern rural GBM represent one of the most vulnerable populations to minority stigma. As such, they are an appropriate population in which to study mental health interventions that target minority stress processes.

#### IV. Review of Transdiagnostic Cognitive Behavioral Interventions

##### *4.1 Transdiagnostic Interventions*

In light of the significant mental and behavioral health challenges experienced by sexual minority individuals, there is a demonstrated need for therapeutic and psychoeducational interventions that target minority stress processes. The syndemic nature of these co-occurring psychiatric disorders and maladaptive behavioral patterns

make transdiagnostic cognitive behavioral therapy (CBT) a viable intervention.<sup>75</sup>

Transdiagnostic CBT differs from standard CBT in terms of the intervention's focus.

Standard CBT protocols often treat one specific diagnosis, such as anxiety;

transdiagnostic CBT, on the other hand, targets symptoms across a range of diagnoses.

The most prominent example of transdiagnostic CBT is the *Unified Protocol for*

*Transdiagnostic Treatment of Emotional Disorders* (UP).<sup>80</sup> The UP works by

implementing a number of therapist-led sessions that first seek to enhance treatment

engagement.<sup>80</sup> Subsequent sessions involve psychoeducation and tracking of emotional

experiences, emotion awareness training, and cognitive appraisal and reappraisal.<sup>80</sup> The

final sessions in the UP involve exploring emotion avoidance and emotionally-driven

behaviors, awareness and tolerance of physical sensations, as well as interoceptive and

situation-based emotion exposures, and relapse prevention.<sup>80</sup> The initial and long-term

efficacy of the UP has been demonstrated in repeated randomized controlled trials.<sup>81,82</sup>

The UP's focus on recognizing the roles of emotion and emotional responses in

dictating maladaptive behaviors is relevant to the problems faced by GBM and other

sexual minorities. The UP's transdiagnostic CBT approach is adaptable to individual

patient needs, and has been shown to be effective in trials using samples of the general

population. An unmodified version of the UP has never been tested among a sample of

GBM, but the targeted universal stress processes and emotional regulation skills in which

the UP is theorized to work would make it appropriate for treating GBM and other sexual

minorities.

A novel psychotherapeutic approach called *Effective Skills to Empower Effective*

*Men* (ESTEEM) builds upon the UP with modifications meant to address the maladaptive

affective, cognitive, and behavioral patterns that derive from minority stress, including depression, anxiety, and health risk behaviors (e.g., substance use, risky sex).<sup>75</sup> In a previous waitlist randomized controlled trial, ESTEEM was found to be efficacious in reducing symptom burden for depression and anxiety, as well as reducing hazardous alcohol consumption and condomless anal sex among GBM.<sup>17</sup> Like the UP, the ESTEEM model cultivates skills for effectively coping with stigma and minority stressors specific to GBM. ESTEEM utilizes various cognitive behavioral techniques, including motivation enhancement, interoceptive and situational exposure, cognitive restructuring, mindfulness, and self-monitoring.<sup>75</sup> The 10 modules that comprise ESTEEM are adapted from the UP to address the specific transdiagnostic processes that exacerbate and maintain minority stress reactions among gay and bisexual men.<sup>75</sup>

#### *4.2 ESTEEM Intervention and Treatment Targets*

The ESTEEM intervention is a step-wise process that begins with a description from the therapist of what the ESTEEM protocol is and how it works. The first session lays important foundations for client understanding and the groundwork for enhancing the client's self-efficacy. The first session also focuses on client's motivation for change and frames the client's mental health problems as a consequence of disproportionate exposure to stigma-related stress.<sup>75</sup> The second session provides more education and context around the relationship between minority stress, mental health, and health risk behaviors. This session focuses on several key points, including the fact that GBM are at greater risk of experiencing mental health problems, and that minority stress works through modifiable mechanisms.<sup>75</sup> Session two continues the process of normalizing the

client's experience with mental health problems, by sharing prevalence data about depression and anxiety among sexual minorities.<sup>75</sup>

Session three introduces the client to the components of emotional experience (i.e., physical sensations, thoughts, behaviors), and to the possibility that minority stress has shaped some components of their emotional experience.<sup>75</sup> This process allows clients to learn more about the adaptive function of emotions and the ways emotions can shape behaviors.<sup>75</sup> Session three also educates the client on how to identify emotional triggers, responses (thoughts, feelings, or behaviors), and consequences.<sup>75</sup> The fourth session builds on the foundation of emotional education established previously, and seeks to help the client accurately identify and describe their emotional reactions. The fourth session also focuses on mindfulness techniques to improve emotional awareness and staying present-focused.<sup>75</sup>

Session five continues to cultivate the client's awareness of the relationship between the emotional experience of minority stress to his negative, rigid, or maladaptive thinking patterns.<sup>75</sup> Such negative or maladaptive thinking patterns that derive from minority stress might include thoughts of inferiority, shame, immorality, abnormality, or unworthiness of love; these negative thoughts and self-appraisals may in turn drive sexual minority clients to engage in unhealthy behaviors, such as seeking status, acceptance, and connection through risky sex or substance use.<sup>75</sup> Session five also introduces the concept of cognitive appraisal, which describes an individual's personal interpretation of a situation and his potential reactions to it. Cognitive appraisal becomes an important tool in that it can allow clients to recognize cognitive distortions based in minority stress;

once challenged, these cognitive distortions can be reappraised, allowing maladaptive cognitive and behavioral patterns to be disrupted.<sup>31,83,75</sup>

In the sixth session the therapist introduces the concept of emotion avoidance, and explores the reasons and strategies client might use to avoid feeling strong emotions.<sup>75</sup> The therapist then highlights the origins in minority stress and stigma. There are also in-session demonstrations of emotion avoidance that involve the client being instructed not to think about a painful memory. This allows the client to observe how emotion avoidance fosters and maintains negative emotions.<sup>75</sup> Session seven focuses on identifying emotion-driven behaviors that derive from minority stress. The therapist leads a discussion on how emotions can dictate behaviors, and how emotion-driven behaviors contribute to long-term negative consequences.<sup>75</sup> The client and therapist then identify emotion-driven behaviors in the client, and work together to change the patterns of emotional responding that lead to emotion-driven behaviors.<sup>75</sup>

The eighth session focuses on assertiveness training. Due to the prevalence of unassertiveness in the lives of many GBM and its documented relationship to minority stress, ESTEEM includes assertiveness training as a unique component of the intervention; assertiveness training does not appear in the UP.<sup>31,75</sup> The training imparts the cognitive and behavioral skills necessary for appropriately managing minority stress and reducing emotion-driven behaviors like avoidance.<sup>75</sup> The ninth session focuses on developing new reactions to minority stress. The session helps clients to confront internal and external emotional triggers in order to allow him to increase his tolerance of emotions and learn new ways to manage emotional reactions. By confronting painful emotional experiences of past and ongoing minority stress during the session, the

underlying emotions lose their power to drive the client's behavior in maladaptive ways.<sup>75</sup> The tenth and final session involves summarizing and reviewing the skills learned and client's progress made throughout the ESTEEM program. The session concludes with a self-affirmation exercise that helps them reflect on their resilience and serves as a relapse prevention approach, like those utilized in the UP.<sup>75</sup>

#### *4.3 Adapting ESTEEM to The Rural South*

Considering the significant need for mental health services among rural GBM in the South, and the lack of adequate mental health care services in many rural areas, a proposed adaptation of the ESTEEM intervention would benefit from utilizing telehealth platform for intervention delivery.<sup>21,84,85</sup> While few if any studies have utilized a specific sexual minority population for the delivery of telehealth-based CBT, various randomized controlled trials have demonstrated the efficacy of telehealth CBT compared to in-person therapy in the general population.<sup>86,26,87</sup> In addition to being cost-effective, a systematic review of rural CBT showed that rural participants were satisfied with the amount of face-to-face time they received through telehealth-delivered CBT.<sup>88</sup> The same systematic review also showed that rural participants did not express confidentiality concerns using telehealth.<sup>88</sup> Thus, telehealth represents an effective and efficient means to deliver ESTEEM and other transdiagnostic CBT protocols to a rural population.

### **V. Review of the LGB-Focused Intervention Literature**

#### *5.1 State of Intervention Research for Sexual Minorities*

While several interventions that target various types of minority stress exist, only one systematic review to date has analyzed the range of options and methodologies

available for LGB-specific psychological interventions.<sup>89</sup> Of the 44 studies analyzed in this LGB-specific intervention “toolkit,” the interventions were implemented in a variety of social contexts, including mental health care, parent-child relationships, and educational institutions.<sup>89</sup> These studies also utilized a variety of methodologies, ranging from randomized controlled trials to case studies with no control group. The majority of the studies were designed to reduce exposure to sexual minority stress in the forms of interpersonal stigma and structural stigma, such as reducing prejudice and increasing interactions between sexual minorities and heterosexuals.<sup>89</sup> Other studies attempted to bolster coping resources, and some focused on both reducing sexual minority stigma and enhancing coping resources.<sup>89</sup>

In terms of interventions designed to reduce minority stressors, these were divided into structural, interpersonal, and individual interventions. One structural intervention to reduce minority stressors in an educational context is the implementation of Gay-Straight Alliances in schools. Gay-Straight Alliances were shown to improve both psychosocial and educational outcomes for sexual minority students.<sup>89,90</sup> An interpersonal intervention in this category sought to teach heterosexuals to decrease anti-LGB discriminatory behavior by increasing contact between homosexuals and heterosexuals; this “contact effect” increases empathy between the two groups and has significant empirical evidence to support it.<sup>89,91</sup> Individual interventions constituted the majority of interventions to reduce minority stress ( $n=23$ ), and most worked by attempting to reduce a heterosexual individual’s stereotyping or prejudicial behavior toward sexual minorities.<sup>89</sup> In terms of multilevel interventions, a prominent example is the Safe Zone program, which works by training faculty and staff at universities to offer supportive environments for LGB

students. The program works by placing stickers in prominent locations, such as office doors. In doing so, it increases visibility for LGB supportive environments and increases the faculty's ability to engage in LGB-affirmative behaviors.<sup>89,92</sup>

The interventions designed to bolster coping skills and strategies can also be divided into interpersonal, individual, and multilevel categories. In terms of individual interventions to increase coping resources, various evidence-based CBT protocols exist.<sup>17,91</sup> For example, a computerized CBT intervention called Rainbow SPARX has shown effectiveness at significantly reducing depressive symptoms among sexual minority youth.<sup>17,91</sup> An HIV risk prevention intervention targeted to Latino GBM called *SOMOS* is an example of a multilevel approach to bolstering coping skills. It works by teaching young men to cope with specific stressors related to their sexual and ethnic identities, such as homophobia and racism. ESTEEM was the only intervention of the 44 studies that sought to develop coping techniques specific to interpersonal relationships; it was also the only study to conduct a randomized controlled trial.<sup>89</sup> By specifically targeting maladaptive emotional avoidance patterns common among GBM, ESTEEM equips participants with the skills to overcome negative emotional avoidant behavior and establish meaningful relationships with friends and partners.<sup>89</sup> The efficacy of ESTEEM was established in a waitlist randomized controlled trial among urban young GBM. The intervention significantly reducing depressive symptoms, alcohol use problems, sexual compulsivity, and condomless anal sex with casual partners compared to waitlist controls.<sup>17</sup>

This literature review provides an overview of the scholarly literature on topics related to the randomized controlled trial proposed hereafter. It provides historical,



empirical, and theoretical context that justifies the need to conduct the proposed ESTEEM trial among rural GBM in the South. The literature review discussed minority stress theory, mental and behavioral health issues among GBM and other sexual minorities, as well as transdiagnostic cognitive behavioral therapies. It went onto to describe the state of LGB-focused mental health interventions, as well as provide greater context around mental health issues among sexual minorities in the rural South. Finally, this review provided necessary detail about the ESTEEM intervention, and how it is theorized to work to improve health outcomes among GBM and other sexual minorities.

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## Chapter 3 – Study Methods

### I. Study Design

The proposed study will be a parallel group randomized controlled trial conducted over twelve months in southeastern states in the US. The study will be conducted in partnership between Yale University researchers and researchers at the University of Alabama at Birmingham (UAB). The sample population will consist of young gay and bisexual men living in rural Alabama, Mississippi, Tennessee, Georgia, and northern Florida. The participants will be randomized to receive either a modified transdiagnostic cognitive behavioral therapy (CBT) intervention targeted to the stigma-related stressors affecting gay and bisexual men (GBM), called *Effective Tools for Empowering Effective Men* (ESTEEM), or control group. The control group will receive an unmodified transdiagnostic CBT protocol called the Unified Protocol for Treatment of Transdiagnostic Treatment of Emotional Disorders (UP).

Baseline, 5-week, 10-week, and 24-week assessments of each primary and secondary outcome will be collected for both the intervention and control groups through a standardized online survey that incorporates questions from reliable and valid outcomes measures. Both the UP group and the ESTEEM groups will receive one CBT session per week, for a total of ten educational sessions required for the ESTEEM and UP protocols, respectively. Each study participant's CBT session in both the ESTEEM and UP groups will be delivered via a secure video-chat-based telehealth platform.



## II. Study Population and Sampling

The sample population will be comprised of young males who identify as gay or bisexual men and reside in rural counties in Alabama, eastern Mississippi, western Georgia, southern Tennessee, or northern Florida. UAB researchers will be responsible for the recruitment of young, rural, gay and bisexual men to be studied. Eligible participants will be enrolled on a continuous basis over the course of a six-month enrollment period. Convenience sampling will be employed through online social media advertisements on popular social media websites targeted to young gay and bisexual men. Interested men will contact research assistants through a link displayed on online ads, or by contacting the telephone number or email provided in the advertisement. To be considered eligible, interested persons must identify as a gay or bisexual man; be between eighteen and thirty-five years old; be fluent in English; reside in a rural county (as defined by US Census Bureau) in Alabama, eastern Mississippi, western Georgia, southern Tennessee, or northern Florida; be HIV negative; have engaged in HIV-risk behavior, defined as condomless anal sex in the past 90 days with a male partner with unknown HIV status or HIV-positive status; have symptoms of depression in the past 90 days; not be regularly receiving mental health services, defined as receiving talk therapy, psychotherapy, or pharmacologic treatment for a diagnosed mental or behavioral health problem at least twice per month; and have a score of eight or more on the Overall Depression Severity and Impairment Scale (ODSIS).

## III. Recruitment

Both control and intervention subjects will be recruited through a marketing campaign that will utilize online advertisements on popular social media sites such as Facebook, sexual networking apps such as Grindr, and ads on internet classified pages such as Craigslist. Traditional media will also be used in the form of posted paper advertisements on message boards at college counseling centers (Appendix H), as well as regional LGBT community centers. The study will also be directly advertised through targeted emails to counselors and outreach workers at community colleges, colleges, and LGBT community centers in the region.

Young men interested in participating in the study will follow a link located on the advertisements to a website that will provide a brief eligibility questionnaire (Appendix G). If a participant is found to be eligible and indicates he would like to be contacted, the website will prompt the interested person to enter his contact information. A research assistant based at UAB will contact the interested person using the contact information provided on the eligibility website. The research assistant will provide a brief explanation of the study's goals, i.e., to improving mental health among the rural gay and bisexual community. After providing more information and confirming interest, the research assistant will provide a potential participant with a detailed explanation of risks, potential benefits, and requirements for study participation, as well as an explanation of informed consent. If the participant accepts the terms and grants informed consent, he will be sent an email with the information clearly stated, as well as a PDF consent form (Appendix F) that can be signed and returned electronically. Following receipt of informed consent, the participant will be randomized to intervention or control. Each

participant will begin either the UP or ESTEEM protocol at the next scheduled appointment time.

#### IV. Study Variables and Operationalization

The independent variable will be *Effective Tools to Empower Effective Men* (ESTEEM). ESTEEM will be delivered by licensed mental health providers with experience delivering CBT. The mental health providers will be trained in the specific delivery protocol of ESTEEM or the UP, depending on study needs. Each participant randomized to intervention will receive one weekly session of ESTEEM via telehealth interface for ten weeks for a total of ten sessions. Baseline and follow up assessments will be conducted using a standardized online survey that will incorporate questions from the fifteen validated primary and secondary outcome measures. Follow up assessments will utilize the same standardized online survey completed by participants at baseline, and will be assessed at 5-weeks, 10-weeks, and 24-weeks. The 5-week assessment time frame was chosen in order to collect data at the midway point in the ESTEEM and UP protocols. The 10-weeks assessment will collect data at the end of the intervention. The 24-weeks assessment will measure durability of the intervention at 6 months following the first ESTEEM or UP session.

The primary dependent variable and main outcome for sample size and power calculation purposes will be depressive symptoms as measured by the Overall Depression Severity and Impairment Scale (ODSIS) (Appendix A). This main outcome will be operationalized as a comparison of mean change from baseline between the intervention

and control groups. Change from baseline at 10 weeks will determine primary effect. Assessment at 24 weeks will provide data on the duration of the intervention's effect.

Four other psychosocial primary outcomes will also be measured, including anxiety symptoms, alcohol use, sexual compulsivity, and condomless anal sex. Anxiety symptoms will be measured using the Overall Anxiety Severity and Impairment Scale (OASIS) (Appendix B). Sexual compulsivity will be measured using the Sexual Compulsivity Scale (SCS) (Appendix E). Alcohol use will be measured using the Alcohol Use Disorders Identification Scale (AUDIT) (Appendix C). Condomless anal sex will be measured using the Safer Sex Self Efficacy Questionnaire (SSSE), as well as the 90 Day Time Line Follow Back (TLFB). The TLFB also measures alcohol use. Each of these psychosocial primary outcomes will be operationalized as a comparison of mean change from baseline in OASIS, SCS, AUDIT, SSSE, and TLFB between the intervention and control groups.

There are three additional secondary dependent variables related to minority stress processes that will be assessed using validated outcome measures, including rejection sensitivity, internalized homophobia, and concealment. These secondary dependent variables will be assessed as secondary outcomes. Rejection sensitivity will be measured using the Gay-Related Rejection Sensitivity Scale (GRS). Internalized homophobia will be measured using the Internalized Homophobia Scale (IHP). Concealment of sexual orientation will be measured using the Sexual Orientation Concealment Scale (SOCS). Additionally, gay-related stress will be assessed using the Measure of Gay-Related Stress (MOGS). Each of the secondary outcomes related to minority stress processes will be

operationalized as mean change from baseline at 10 weeks in GRS, SOCS, and MOGS between the intervention and control groups.

There will be an additional category of secondary dependent variables related to universal stress processes, which include rumination, emotion dysregulation, lack of social support, and unassertiveness. These secondary dependent variables will be assessed as secondary outcomes. Rumination will be measured using the Ruminative Responses Scale (RRS). Emotion dysregulation will be measured using the Difficulties of Emotion Regulation Scale (DERS). A lack of social support will be gauged with the Multidimensional Scale of Perceived Social Support (MSPSS). Unassertiveness will be assessed using the Rathus Assertiveness Schedule (RAS). Each of the secondary outcome measures related to universal stress processes will be operationalized as mean change from baseline at 10 weeks in RRS, DERS, MSPSS, and RAS between the intervention and control groups.

Analyses will be stratified by age, income, race and ethnic group, education level, and severity of depressive symptoms as defined by the ODSIS.

## V. Randomization, Assignment and Blinding

Enrolled participants will be randomized on a 1:1 basis to intervention and control groups. Each participant will receive a six-digit randomly generated identification number. This six-digit number will facilitate blinding at the level of research personnel involved with data collection and analysis. Randomization and number assignment will be performed using a free, open-source, web-based randomization tool called Research Randomizer (randomizer.net). The program will randomly allocate each participant to either intervention or control group following confirmation of eligibility. The research

assistant involved in assigning participants to study groups will only disclose group assignments to the mental health professionals administering the CBT intervention and control protocols. All research assistants involved in participant interviews for timeline follow back and risk behavior assessments will be blind to participant condition assignment. The research assistant who works in allocation will not perform timeline follow back assessments of risk behavior. Participants will complete assessment surveys on private computers to minimize experimenter bias. Mental Health providers administering the intervention will not formally be made aware of study hypothesis to minimize observer-expectancy effect.

## VI. Data Collection

Data will be collected by means of a standardized, web-based survey that will incorporate questions from each of the validated outcome measures into one comprehensive survey. The assessment survey will exist on a password-controlled website. Participants will be emailed links to the standardized survey website for baseline assessment. Participants will provide their six-digit ID codes for anonymity while completing online assessments. Participants will then be allowed four days to complete the survey, with up to two reminders via email and/or phone calls from a research assistant. Email communications will provide anticipatory guidance on how long participants should expect the survey to take to complete, as well as information on how the data collected will be securely stored. Each follow-up survey taken at 5-weeks, 10-weeks, and 24-weeks will use the same standardized survey.

## VII. Adherence

All sessions will be recorded through the video conferencing feature of the telehealth software through which ESTEEM and UP will be delivered. Two trained mental health professionals with expertise in the delivery of ESTEEM and the UP will review the recordings of each session to assess the fidelity of the treatment delivery using a standardized fidelity checklist. Fidelity checklists will be specific to each session and will contain between five and ten items that rate the interviewer's delivery of ESTEEM or the UP on a scale from 0 (topic not covered at all) to 2 (topic covered thoroughly). Sessions will be coded for cross-arm contamination alongside fidelity ratings.

## VIII. Sample Size Calculation

Sample size calculations were made using the free PC program *PS: Power and Sample Size Calculation version 3.2.2, 2014*. The sample size was calculated using a two-sided two sample *t*-test with alpha of 0.05 to achieve 80% power to detect a significant difference between the null and alternative hypothesis, assuming a 25% drop out rate. A meta-analysis of 65 experimental studies of culturally-adapted psychotherapy showed an omnibus effect size of  $d=0.46$ .<sup>97</sup> Using the average effect size of  $d=0.46$ , we would need a sample size of 152 total participants, or 76 per study arm, to achieve a power of 0.80 (Appendix I). This sample size calculation adjusts for a 25% estimated attrition rate, which is conservative given the attrition rates of 10-20% in previous ESTEEM studies.<sup>17</sup>

## IX. Statistical Analysis

The mean between-group differences in outcome variables for each primary and secondary outcome will be assessed using an intention-to-treat analysis, in which all participants will be analyzed according to their randomized group assignment, regardless of level of treatment participation. Mean between-group differences in the primary and secondary outcomes will be tested for significance with *t*-tests. If there are any significant between-group differences, then multiple linear regression models will be used to adjust for covariates including age, income, race, education level, and severity of depressive symptoms. Unadjusted and covariate-adjusted ANCOVA regression models will be used to test associations between treatment participation and specific mental health and behavioral health changes, such as overall change in depressive symptoms. An additional condition X number of sessions interaction will be used to assess if degree of participation will produce a dose-effect.

#### X. Subject Protection and Confidentiality

This proposal will be submitted to the Yale University Institutional Review Board (IRB) and to the UAB Institutional Review Board for Human Use for consideration and approval prior to the execution of the research protocols described. An application and supporting documents will also be submitted to the Human Subjects Committee (HSC) at Yale University for consideration and approval prior to initiation of study protocols. All members of the team will undergo Human Subjects Protection Training through the Human Research Protection Program at Yale University. Due to the fact that the study is offering an educational intervention that will not be collecting federally protected health information about subjects, researchers are not required to be trained in HIPPA. Informed



consent will be required of all participants to be considered for enrollment in the proposed study. Documentation provided to participants to gain consent will include thorough explanations of study procedures and details, including any anticipated benefits and risks. Unwillingness or incapacity to complete the consent process will render potential participants ineligible for study participation.

All information pertaining to the participants will be held in confidence and will be accessible only by the research team involved in the study. In accordance with any applicable state and federal laws, all protected participant information will be securely stored and accessed in password-protected files on password-protected computers. Only one document (a linking document for safety purposes, e.g., clinical emergency) will link participants' names to their six-digit identification numbers. All other databases will be de-identified (i.e., contain only IDs, no other identifying information). All data will be stored on Yale's Box, which meets Yale's institutional and legal requirements for storing unpublished research data. No physical participant records will be maintained. All clinicians and research staff involved will be required to sign a confidentiality contract. Potential participants will be made aware that their participation in the trial is entirely voluntary and may be terminated at any time. Participants will be informed that withdrawal will not affect the eligibility of participant for future research studies or the ability to receive future care for medical, psychiatric, mental health, or behavioral health conditions.

## XI. Timeline and Resources

Per the guidelines for the proposal, the study will take place during a maximum 2-year time frame, which includes recruitment, follow-up, and data analysis. The following is a timeline of dates for different phases of the study, along with a description of necessary research personnel and required resources for study execution.

*August 2018: Approval Phase*

The study proposal will be submitted for approval to both the Yale University Institutional Review Board and to the UAB Institutional Review Board.

*October 2018 – January 2019: Organization Phase*

Mental health clinicians will be recruited from the faculty of the Yale University School of Medicine, Yale University Department of Psychology, UAB School of Medicine, as well as the UAB Department of Psychology. Clinicians with interest in participating in the program will receive free training in the Unified Protocol or the ESTEEM protocol depending on the needs of the study and clinician interest. Clinicians will receive one week of training in the Unified Protocol, delivered through the Unified Protocol Institute's online training program. The training will result in certification in competence in UP administration. Clinicians who receive training in the ESTEEM protocol will do so through online training sessions with experts based at the ESTEEM Center in New York City. Training in ESTEEM will also last for one week.

*February 2019 – July 2019: Recruitment and Enrollment*

Six months will be allotted for recruitment, which will occur on a rolling basis. This allows recruitment of at least 25 participants per month to meet the sample size requirements of 152 subjects.

*August 2019 – January 2020: Data Collection*

Baseline measurements will be collected shortly after enrollment, and follow-up measures will be collected at 5-weeks, 10-weeks, and 24-weeks from the start of the intervention. This phase of the study will overlap with recruitment and occur on a rolling basis.

*February 2020-July 2020: Data Analysis*

Data collected throughout the intervention period will be analyzed by study investigators with the assistance of a biostatistician.

*Personnel and Resources:*

Study personnel will include a principle investigator (PI), co-PI, research assistants, a website developer, IT support, a biostatistician, an advertising consultant, and a graphic design consultant. Mental health clinicians will be asked to participate in the study on a voluntary basis and to undergo training in either ESTEEM or the UP. The same clinician will deliver the ESTEEM or UP to the same participant for all 10 sessions to establish and maintain rapport and a therapeutic relationship. Clinicians will be delivering either ESTEEM or the UP (not both) in order to prevent arm contamination. Clinicians will be encouraged to not speak to colleagues about the CBT protocol they are administering in order to decrease the chances of cross-arm contamination. Clinicians will not be involved in data collection or analysis. Research assistants, such as graduate students, will provide measurement, data collection, and enrollment functions. A senior member of the research team will oversee data collection and management. As many researchers participating in data collection and analysis as possible will be blinded during the study period and follow-up. Some researchers will have to be unblinded for tracking participants and scheduling appointments. IT support will be available for any issues

with the study website or telehealth platform. Special equipment required of all clinicians will include a computer or other electronic device with a webcam and a secure, high-speed internet connection. No rental spaces will be required.

Sufficient funding will be required to compensate research and operations staff, as well as clinicians for their time spent delivering the UP or ESTEEM protocols. Funding will be required to cover the cost of training clinicians in the new protocols. A budget will need to allocate sufficient funds for the online advertisements and marketing used in recruitment, as well as the graphic design of the ads. The budget will also need to include a limited number of clerical and printing supplies to create printed materials.

### Chapter 3 References

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## Chapter 4 – Conclusion

### I. Advantages

The proposed study has several conceptual and practical advantages. The first is that the ESTEEM protocol is an evidence-based cognitive behavioral intervention that is based on empirically-supported components of minority stress theory. ESTEEM was developed by experienced mental health providers in collaboration with gay and bisexual men affected by mental health problems. ESTEEM's GBM-affirmative message and content promote resilience, personal agency, and improved interpersonal relationships.<sup>89</sup> ESTEEM and the Unified Protocol are transdiagnostic platforms, which is a practical strength for both in that transdiagnostic CBT protocols circumvent the need to train providers in multiple standard CBT protocols to treat specific diagnoses. Utilizing a telehealth-based delivery model will allow the protocols to reach a wider array of rural participants while presenting cost savings in terms of travel and treatment facility overhead costs. Telehealth has the added benefit of decreasing transportation costs and other financial barriers to adherence and retention among participants.

The proposed study has a number of methodological strengths as well. It will be the first randomized controlled trial to compare the efficacy of a GBM-affirmative transdiagnostic CBT to a control group receiving standard transdiagnostic CBT. As such, the study will allow researchers sufficient data to establish whether additions to the ESTEEM protocol (e.g., assertiveness training) improve outcomes over existing transdiagnostic treatments like the UP. Moreover, this study's use of a stronger control group than previous preliminary trials will further establish the efficacy of GBM-affirmative CBT compared to existing treatments. It will also contribute to efficacy data

for ESTEEM established in previous trials.<sup>17,24</sup> The proposed study is adequately powered to detect a meaningful effect size, while using an achievable sample size and realistic timeframe. A randomized controlled trial also offers methodological advantages, such as the ability to control for potential confounders, including operational confounding. Randomization of assignments and blinding of investigators (except those tracking adherence and performing administrative tasks) will prevent bias, such as sampling bias. Utilizing reliable and valid outcome measures for study variables will decrease information bias and allow reproducibility of the proposed study's findings in subsequent studies. Finally, the study will attempt to recruit a diverse sample of rural GBM so that results will be generalizable to a larger population.

## II. Disadvantages

There are some disadvantages to the proposed study. At this point, ESTEEM is the only intervention of its kind that addresses the specific co-occurring mental and behavioral health needs of sexual minority men. Thus, sexual minority women and transgender individuals are currently excluded from receiving the treatment protocol, though ESTEEM adaptation research is currently underway for use among a sexual minority women.<sup>75</sup> In terms of methodological disadvantages, the study's outcome measures rely on non-diagnostic self-report scales with non-standardized time frames. For example, some scale might ask about symptoms in the past month, while another asks about the presence of symptoms in general. These discrepancies are thought to have affected measures of minority stress in a previous ESTEEM trial.<sup>17</sup> Additionally, the fact that recruitment depends on self-identified GBM accessing information about the trial

through GBM-specific websites could introduce sampling bias toward GBM who are more open about their sexuality, and therefore experience fewer proximal minority stress processes. Moreover, while participants will be selected who have mental health problems and sexual risk behaviors, there is no guarantee that enrolled participants will necessarily be experiencing minority stress processes. Finally, a significant limitation is that the study excludes GBM without access to high-speed internet and an internet-connected device. However, this limitation is becoming less relevant with the expansion of nationwide broadband and increased utilization of mobile phones among all socioeconomic levels.<sup>95</sup>

### III. Clinical and Public Health Significance

ESTEEM represents a promising public health tool considering the significant emotional and financial costs, as well as lifetime persistence, of health disparities facing GBM.<sup>96</sup> While not able to address structural stigma directly, ESTEEM promotes health among GBM through teaching stigma-coping skills. These improved coping resources empower GBM to confront both interpersonal and structural stigma more effectively. At a clinical level, incorporating elements of ESTEEM into a primary care setting for HIV-positive men could impart coping skills that mitigate sexual minority stigma as well as HIV-related stigma. Incorporating ESTEEM into HIV-prevention services and HIV-continuum of care would expand minority stress-targeted mental health treatment to people who might not otherwise access mental healthcare.<sup>75</sup> Moreover, ESTEEM is a treatment that can be modified and expanded to other regions of North America as well as globally. In expanding minority stress treatment models to other regions, particular



attention should be paid to the distinct features of various geographic locations, particularly rural ones, that underlie particularly high minority stressors and their accompanying health disparities.

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## Appendices

### Appendix A

#### **Overall Depression Severity and Impairment Scale (ODSIS)**

The following items ask about depression. For each item, select the number for the answer that best describes your experience over the past week.

1. In the past week, how often have you felt depressed?

0 = No depression in the past week.

1 = Infrequent depression. Felt depressed a few times.

2 = Occasional depression. Felt depressed as much of the time as not. 3 = Frequent depression. Felt depressed most of the time.

4 = Constant depression. Felt depressed all of the time.

2. In the past week, when you have felt depressed, how intense or severe was your depression?

0 = Little or None: Depression was absent or barely noticeable. 1 = Mild: Depression was at a low level.

2 = Moderate: Depression was intense at times.

3 = Severe: Depression was intense much of the time.

4 = Extreme: Depression was overwhelming.

3. In the past week, how often did you have difficulty engaging in or being interested in activities you normally enjoy because of depression?

0 = None: I had no difficulty engaging in or being interested in activities that I normally enjoy because of depression.

1 = Infrequent: A few times I had difficulty engaging in or being interested in activities that I normally enjoy, because of depression. My lifestyle was not affected.

2 = Occasional: I had some difficulty engaging in or being interested in activities that I normally enjoy, because of depression. My lifestyle has only changed in minor ways.

3 = Frequent: I have considerable difficulty engaging in or being interested in activities that I normally enjoy, because of depression. I have made significant changes in my lifestyle because of being unable to become interested in activities I used to enjoy.

4 = All the Time: I have been unable to participate in or be interested in activities that I normally enjoy, because of depression. My lifestyle has been extensively affected and I no longer do things that I used to enjoy.

4. In the past week, how much did your depression interfere with your ability to do the things you needed to do at work, at school, or at home?

0 = None: No interference at work/home/school from depression

1 = Mild: My depression has caused some interference at work/home/school. Things are more

difficult, but everything that needs to be done is still getting done.

2 = Moderate: My depression definitely interferes with tasks. Most things are still getting done, but

few things are being done as well as in the past.

3 = Severe: My depression has really changed my ability to get things done. Some tasks are still being

done, but many things are not. My performance has definitely suffered.

4 = Extreme: My depression has become incapacitating. I am unable to complete tasks and have had

to leave school, have quit or been fired from my job, or have been unable to complete tasks at home and have faced consequences like bill collectors, eviction, etc.

5. In the past week, how much has depression interfered with your social life and relationships?

0 = None: My depression doesn't affect my relationships.

1 = Mild: My depression slightly interferes with my relationships. Some of my friendships and other relationships have suffered, but, overall, my social life is still fulfilling.

2 = Moderate: I have experienced some interference with my social life, but I still have a few close relationships. I don't spend as much time with others as in the past, but I still socialize sometimes.

3 = Severe: My friendships and other relationships have suffered a lot because of depression. I do not

enjoy social activities. I socialize very little.

4 = Extreme: My depression has completely disrupted my social activities. All of my relationships have suffered or ended. My family life is extremely strained.

TOTAL: \_\_\_\_\_

Accessed from:

<http://www.oxfordclinicalpsych.com/view/10.1093/med:psych/9780199772674.001.0001/med-9780199772674-interactive-pdf-002.pdf>

## Appendix B

Subject ID Number: \_\_\_\_\_

Date: \_\_\_\_\_

### Overall Anxiety Severity and Impairment Scale (OASIS)

The following items ask about anxiety and fear. For each item, circle the number for the answer that best describes your experience *over the past week*.

1. In the past week, how often have you felt anxious?
  - 0 = *No anxiety* in the past week.
  - 1 = *Infrequent anxiety*. Felt anxious a few times.
  - 2 = *Occasional anxiety*. Felt anxious as much of the time as not. It was hard to relax.
  - 3 = *Frequent anxiety*. Felt anxious most of the time. It was very difficult to relax.
  - 4 = *Constant anxiety*. Felt anxious all of the time and never really relaxed.
2. In the past week, when you have felt anxious, how intense or severe was your anxiety?
  - 0 = *Little or None*: Anxiety was absent or barely noticeable.
  - 1 = *Mild*: Anxiety was at a low level. It was possible to relax when I tried. Physical symptoms were only slightly uncomfortable.
  - 2 = *Moderate*: Anxiety was distressing at times. It was hard to relax or concentrate, but I could do it if I tried. Physical symptoms were uncomfortable.
  - 3 = *Severe*: Anxiety was intense much of the time. It was very difficult to relax or focus on anything else. Physical symptoms were extremely uncomfortable.
  - 4 = *Extreme*: Anxiety was overwhelming. It was impossible to relax at all. Physical symptoms were unbearable.
3. In the past week, how often did you avoid situations, places, objects, or activities because of anxiety or fear?
  - 0 = *None*: I do not avoid places, situations, activities, or things because of fear.
  - 1 = *Infrequent*: I avoid something once in a while, but will usually face the situation or confront the object. My lifestyle is not affected.
  - 2 = *Occasional*: I have some fear of certain situations, places, or objects, but it is still manageable. My lifestyle has only changed in minor ways. I always or almost always avoid the things I fear when I'm alone, but can handle them if someone comes with me.
  - 3 = *Frequent*: I have considerable fear and really try to avoid the things that frighten me. I have made significant changes in my life style to avoid the object, situation, activity, or place.
  - 4 = *All the Time*: Avoiding objects, situations, activities, or places has taken over my life. My lifestyle has been extensively affected and I no longer do things that I used to enjoy.
4. In the past week, how much did your anxiety interfere with your ability to do the things you needed to do at work, at school, or at home?
  - 0 = *None*: No interference at work/home/school from anxiety
  - 1 = *Mild*: My anxiety has caused some interference at work/home/school. Things are more difficult, but everything that needs to be done is still getting done.
  - 2 = *Moderate*: My anxiety definitely interferes with tasks. Most things are still getting done, but few things are being done as well as in the past.
  - 3 = *Severe*: My anxiety has really changed my ability to get things done. Some tasks are still being done, but many things are not. My performance has definitely suffered.
  - 4 = *Extreme*: My anxiety has become incapacitating. I am unable to complete tasks and have had to leave school, have quit or been fired from my job, or have been unable to complete tasks at home and have faced consequences like bill collectors, eviction, etc.

\*Continued on the back of this page...

Subject ID Number: \_\_\_\_\_

Date: \_\_\_\_\_

5. In the past week, how much has anxiety interfered with your social life and relationships?

0 = *None*: My anxiety doesn't affect my relationships.

1 = *Mild*: My anxiety slightly interferes with my relationships. Some of my friendships and other relationships have suffered, but, overall, my social life is still fulfilling

2 = *Moderate*: I have experienced some interference with my social life, but I still have a few close relationships. I don't spend as much time with others as in the past, but I still socialize sometimes.

3 = *Severe*: My friendships and other relationships have suffered a lot because of anxiety. I do not enjoy social activities. I socialize very little.

4 = *Extreme*: My anxiety has completely disrupted my social activities. All of my relationships have suffered or ended. My family life is extremely strained.

## Appendix C

### AUDIT questionnaire

**Please circle the answer that is correct for you**

1. How often do you have a drink containing alcohol?

- Never
- Monthly or less
- 2-4 times a month
- 2-3 times a week
- 4 or more times a week

2. How many standard drinks containing alcohol do you have on a typical day when drinking?

- 1 or 2
- 3 or 4
- 5 or 6
- 7 to 9
- 10 or more

3. How often do you have six or more drinks on one occasion?

- Never
- Less than monthly
- Monthly
- Weekly
- Daily or almost daily

4. During the past year, how often have you found that you were not able to stop drinking once you had started?

- Never
- Less than monthly
- Monthly
- Weekly
- Daily or almost daily

5. During the past year, how often have you failed to do what was normally expected of you because of drinking?

- Never
- Less than monthly
- Monthly
- Weekly
- Daily or almost daily

6. During the past year, how often have you needed a drink in the morning to get yourself going after a heavy drinking session?

- Never
- Less than monthly
- Monthly
- Weekly
- Daily or almost daily

7. During the past year, how often have you had a feeling of guilt or remorse after drinking?

- Never
- Less than monthly
- Monthly
- Weekly
- Daily or almost daily

8. During the past year, have you been unable to remember what happened the night before because you had been drinking?

- Never
- Less than monthly
- Monthly
- Weekly
- Daily or almost daily

9. Have you or someone else been injured as a result of your drinking?

- No
- Yes, but not in the past year
- Yes, during the past year

10. Has a relative or friend, doctor or other health worker been concerned about your drinking or suggested you cut down?

- No
- Yes, but not in the past year
- Yes, during the past year

#### Scoring the AUDIT

Scores for each question range from 0 to 4, with the first response for each question (eg never) scoring 0, the second (eg less than monthly) scoring 1, the third (eg monthly) scoring 2, the fourth (eg weekly) scoring 3, and the last response (eg. daily or almost daily) scoring 4. For questions 9 and 10, which only have three responses, the scoring is 0, 2 and 4 (from left to right).

A score of 8 or more is associated with harmful or hazardous drinking, a score of 13 or more in women, and 15 or more in men, is likely to indicate alcohol dependence.

Saunders JB, Aasland OG, Babor TF et al. Development of the alcohol use disorders identification test (AUDIT): WHO collaborative project on early detection of persons with harmful alcohol consumption — II. *Addiction* 1993, 88: 791–803.



## Appendix D

### Center for Epidemiologic Studies Depression Scale (CES-D), NIMH

Below is a list of the ways you might have felt or behaved. Please tell me how often you have felt this way during the past week.

	During the Past			
	Week			
	Rarely or none of the time (less than 1 day )	Some or a little of the time (1-2 days)	Occasionally or a moderate amount of time (3-4 days)	Most or all of the time (5-7 days)
1. I was bothered by things that usually don't bother me.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. I did not feel like eating; my appetite was poor.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. I felt that I could not shake off the blues even with help from my family or friends.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. I felt I was just as good as other people.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. I had trouble keeping my mind on what I was doing.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. I felt depressed.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. I felt that everything I did was an effort.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. I felt hopeful about the future.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. I thought my life had been a failure.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. I felt fearful.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. My sleep was restless.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. I was happy.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. I talked less than usual.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14. I felt lonely.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15. People were unfriendly.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16. I enjoyed life.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
17. I had crying spells.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
18. I felt sad.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
19. I felt that people dislike me.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
20. I could not get "going."	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**SCORING:** zero for answers in the first column, 1 for answers in the second column, 2 for answers in the third column, 3 for answers in the fourth column. The scoring of positive items is reversed. Possible range of scores is zero to 60, with the higher scores indicating the presence of more symptomatology.

## Appendix E

### Sexual Compulsivity Scale

The Sexual Compulsivity Scale was developed to assess tendencies toward sexual preoccupation and hypersexuality. Items were initially derived from self-descriptions of persons who self-identify as having a 'sexual addiction'. The self-descriptors were taken from a brochure for a sexual addictions self-help group. The scale has been shown to predict rates of sexual behaviors, numbers of sexual partners, practice of a variety of sexual behaviors, and histories of sexually transmitted diseases. The scale is internally consistent with Alpha coefficients that range between .85 and .91.

### References

Benotsch, E.G., Kalichman, S.C., and Pinkerton, S.D. (2001). Sexual Compulsivity in HIV-Positive Men and Women: Prevalence, Predictors, and Consequences of High-Risk Behaviors. *Sexual Addiction and Compulsivity: Journal of Treatment and Prevention* 8, 83-99.

Kalichman, S.C. and Rompa, D. (2001). The Sexual Compulsivity Scale: Further Development and Use with HIV Positive Persons. *Journal of Personality Assessment*, 76, 379-395.

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Kalichman, S.C., Adair, V., Rompa, D., Multhauf, K., Johnson, J., and Kelly, J. (1994). Sexual Sensation-Seeking: Scale Development and Predicting AIDS-Risk Behavior Among Homosexually Active Men. *Journal of Personality Assessment*, 62, 385-397.

**A number of statements that some people have used to describe themselves are given below. Read each statement and then circle the number to show how well you believe the statement describes you.**

	<b>Not at all like me</b>	<b>Slightly like me</b>	<b>Mainly like me</b>	<b>Very Much like me</b>
1. My sexual appetite has gotten in the way of my relationships.	1	2	3	4
2. My sexual thoughts and behaviors are causing problems in my life.	1	2	3	4
3. My desires to have sex have disrupted my daily life.	1	2	3	4
4. I sometimes fail to meet my commitments and responsibilities because of my sexual behaviors.	1	2	3	4
5. I sometimes get so horny I could lose control.	1	2	3	4
6. I find myself thinking about sex while at work.	1	2	3	4
7. I feel that sexual thoughts and feelings are stronger than I am.	1	2	3	4
8. I have to struggle to control my sexual thoughts and behavior.	1	2	3	4
9. I think about sex more than I would like to.	1	2	3	4
10. It has been difficult for me to find sex partners who desire having sex as much as I want to.	1	2	3	4

To Score: Add items that have responses and divide by number of items responded.

## Appendix F

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### YALE UNIVERSITY, YALE SCHOOL OF PUBLIC HEALTH UNIVERSITY OF MIAMI, DEPARTMENT OF PSYCHOLOGY

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#### Consent for Participation in a Research Study

*A unified intervention for young gay and bisexual men's minority stress,  
mental health, and HIV risk.*

Under the supervision of John E. Pachankis, PhD and Steven A. Safren, PhD

#### PURPOSE AND BACKGROUND

Dr. John Pachankis at Yale University and Dr. Steven Safren at the University of Miami are conducting research about mental health, sexual behavior, and ways of coping with stress among gay and bisexual men. The purpose of this study is to test a type of counseling, called ESTEEM, to help gay and bisexual men improve their mental health, including depression and anxiety, reduce their HIV risk, such as having sex without a condom in the absence of HIV pre-exposure prophylaxis (PrEP) or having sex under the influence of drugs or alcohol, and improve their ability to cope with negative emotions and stress. We anticipate that 250 men between the ages of 18 and 35 will participate in this study. Should you choose to participate in this study, you may complete the study tasks, outlined in detail below, and receive between \$225 and \$325.

#### PROCEDURES

1. **Informed Consent:** Today you will review this informed consent form with a research staff member and sign your name if you agree to participate in this study once all of your questions have been addressed by the research staff member.
2. **Today's Appointment:** During today's appointment a trained research staff member will interview you to ask you questions about your mental health; this interview will be video recorded but the camcorder will face our research staff, not you, though your voice will be recorded. During the interview you will discuss your sexually transmitted disease (STD) risk, your sexual behavior, and take a rapid HIV test and test for chlamydia and gonorrhea. This study utilizes the OraQuick HIV rapid test that is approved for HIV-1 and HIV-2 testing, which allows you to receive your results within 20-30 minutes. If your test result is positive or inconclusive, we will refer you to one of our community partners for an additional confirmatory blood draw test and if you do not have insurance or cannot afford the costs of the further confirmatory testing, the clinic we refer you to has systems in place to cover these costs for you. This study is only open to men who are HIV-negative; therefore, a positive HIV test will make you ineligible for this study. For the chlamydia and gonorrhea tests you will be instructed on how to provide a urine sample, rectal swab, and oral swab in our private office restroom and we will send these samples to a lab for testing. We will notify you of the results as soon as we receive the test results from the laboratory (within two weeks); if test results show that you have chlamydia or gonorrhea, we will refer you to receive treatment for these conditions at a community health provider or your own doctor. We are also required by New York State law to report positive tests to the Department of Health for monitoring. If you test positive for either chlamydia or gonorrhea, we must send your name, age, date of birth, phone number, address, and date of result. You will not be contacted by the Department of Health nor will you face any consequences for your STI status. Testing positive on either STI test will not affect your eligibility in the study. Today's appointment will take about two hours and you will receive \$25 for completing this appointment.
3. **Second Appointment:** Depending on your schedule, you will return to our office in about one week for a second appointment that will last approximately two hours. Prior to the appointment, you will be emailed a survey that will take about an hour to complete and can be completed wherever you feel most comfortable. This survey will ask you questions about your mental health, sexual behavior, and ways of coping with the

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stress you might have experienced because of your sexual orientation. If you do not have an email address, internet, or access to a computer, we can arrange for you to complete the survey in our office. During the second appointment, you will complete an interview and in-office computer-based tasks with a research staff member. Just as today, the interview will be video recorded, but the camcorder will only face our research staff, not you. At the end of the appointment, you will be randomly assigned by computer to one of three conditions: (a) 10 sessions of counseling in our offices, (b) 10 sessions of counseling in the offices of community mental health providers (the Institute for Human Identity if you are in New York or Care Resources if you are in Miami), or (c) no counseling. If you are assigned to the no counseling condition, we will still invite you to complete the follow-up survey and interview appointments in four months, eight months, and twelve months. You will receive \$25 for completing this second baseline appointment.

4. **If You Receive Counseling:** If you are assigned to receive counseling, you will meet for 10 weekly sessions with a counselor either in our office or in the office of a community mental health provider to discuss your mental health, sexual behavior, and ways of coping with stress and negative emotions. These 10 sessions must be completed within 4 months. After 4 months, you will not receive any more compensated sessions on behalf of the research study. You and your counselor might discuss skills and exercises to help with coping with negative emotions that might be related to negative experiences you have faced (like discrimination and stigma) because of your sexual orientation. Your counselor might ask you to practice skills or complete exercises (like worksheets or activities tracking the way you feel each day) between your counseling sessions so that you can learn how to use them in your daily life. Some of the skills and exercises might make you feel temporarily uncomfortable, like feeling sad or anxious. These sessions will be video recorded for research and supervision purposes; therefore, video recording is not optional. Your counselor will take notes on each session and securely store those notes; your name will not be attached to the notes, only your ID number. You will be compensated \$10 for each session completed (\$100 total for completing all 10 sessions).
5. **4-Month, 8-Month, and 12-Month Follow-up Appointments:** Regardless of whether you were randomly assigned to receive therapy in our offices, the office of a community mental health provider, or no counseling, you will complete in-office surveys and interview appointments at four months from now, eight months from now, and 12 months from now. During the final appointment, we will repeat the rapid HIV testing and STD testing, but not during the appointments taking place four months or eight months from now. The procedures for HIV and STD testing during the 12-month appointment will be identical to the procedures we do during today's initial appointment, as described above. You will receive \$50 for the 4-month and 8-month appointments. For your final appointment, the 12-month follow-up, you will receive \$75. If you complete your 4-month follow-up, 8-month follow-up, and 12-month follow-up appointments you will be entered into a sweepstakes, where you can win an additional \$200.

## CONFIDENTIALITY AND THE PROTECTION OF YOUR PRIVACY

We will guard your confidentiality and protect all information about you and your participation in this study to the extent permitted by law. The following procedures will be followed in an effort to keep your personal information confidential and private in this study.

Your identity will be held strictly confidential by project staff, who are trained not to discuss any details of this study with individuals outside of this project. All information you provide (emails, worksheets, the video files from your interview) will be encrypted and stored on our research center's secure server and your name will not be attached to this information. You will be given a unique identification number and asked not to discuss any personally identifiable information (for example, your name, address, the names of sex partners) during the duration of your participation to minimize breach of confidentiality. However, if you decide to share your study information with people other than our staff, then your privacy might be compromised.

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To track and schedule your participation in this study, we will use your unique identification number. Information that links your name to your identification number will be kept in a password-protected database stored on a secure server, to which only Dr. John Pachankis, Dr. Steven Safren, and the study staff will have access. We will keep four separate electronic and password-protected files. The first will be a database containing the contact information that you are willing to provide to us for scheduling the study appointments (including your telephone number, email address, mailing address, and date of birth). The second will be the information that you provided in your survey and interview appointments, which the study team will review to determine how well this program works and to ensure that our counselors are properly addressing the topics of your discussions. The third will be the digital video recordings from the interview appointments and counseling sessions. The fourth will track study payments made to you. Only the first database will contain your name, while the others will only contain your identification number. The database with your contact information will be deleted three years after the completion of the study, unless you have expressed interest in being informed of possible future studies. Your name will not be used in any reports or publications from this study. All data you provide for this study will be maintained securely by our study staff for minimum of three years after the study ends.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects.

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

The Certificate of Confidentiality does not prevent the researchers from disclosing voluntarily, without your consent, information that would identify you as a participant in the research project if you tell us of your intent to harm yourself or others (including reporting behaviors consistent with child or elderly abuse). In these cases, confidentiality will be waived and actions may be taken to protect you and/or others. It is your right to decline or stop participation at any time without penalty, should you feel uncomfortable for any reason. If you have any concerns, you may contact the project staff at any point.

## **RISKS**

The physical risks of participation are minimal. As with any research study that collects information about you, there is a risk of breach of confidentiality. However, we will minimize that risk by assigning you a unique study identification number. No identifiers (for example, your name, address, email, date of birth, social security number) will be collected on the survey, interview, or counseling sessions. A record that will link unique identification codes with names and contact information for participants will be accessible only to study staff and maintained in a password-protected file on a secure server at our center.

There is a slight chance that you may feel uncomfortable or embarrassed answering some of the questions that may arise in your conversations with the counselor. You have the option of refusing to answer questions, by stating "I do not wish to answer this question." If any of the questions concern you or cause you to feel distress, you may at any time speak privately with Dr. Pachankis, Principal Investigator of the ESTEEM study, or Dr. Steven Safren, Co-Investigator and director of the ESTEEM study in Miami, both of whom are available by

APPROVED BY THE YALE UNIVERSITY IRB 10/27/2017 VALID THROUGH 8/30/2018

phone or in-person at our New York and Miami research centers.

## **BENEFITS**

It is possible that you may receive benefits from participating in this study. You may learn more about yourself and your mental health, sexual life, and ways of managing stress and negative emotions. You are also helping Dr. Pachankis, Dr. Safren, and their research teams develop a counseling program to reduce mental health and HIV risk for gay and bisexual men who experience depression and anxiety, which will likely benefit other members of the community.

## **COMPENSATION & COSTS**

You will receive the following compensation for completing each portion of the study:

- ☐ The first in-office interview appointment (baseline 1): \$25
- ☐ The second in-office interview appointment (baseline 2): \$25
- ☐ Ten counseling sessions (for those participants who are randomly assigned to receive counseling): \$10 per session, equaling a total of \$100.
- ☐ The 4-month in-office interview appointment: \$50
- ☐ The 8-month in-office interview appointment: \$50
- ☐ The 12-month in-office interview appointment: \$75
- ☐ There will be no cost to you if you participate in this study.

You will be paid the amounts described above after completing each part of the study. If you withdraw from the study, you can keep the compensation that you have earned up to that point, but you will not receive compensation for those parts of the study that you have not completed.

### **Sweepstakes**

- ☐ Annual \$200 Sweepstakes: Each October, starting in October of 2018, participants who have successfully completed all of their follow-up appointment assessments (4-, 8-, and 12-month) will be entered into a sweepstakes to win a \$200 gift card. The winner will receive their gift card via email directly after the drawing. We expect 150 men to enroll over the course of the study, so you would have an approximately 1/30 chance of winning the annual sweepstakes.
- ☐ Monthly Follow-up Appointment Sweepstakes: Every month the research team will hold a sweepstakes for a \$20 gift card for participants who have successfully completed their scheduled follow-up appointments in the previous month. We hold approximately 10 follow-up appointments per month, so we anticipate that you would have an approximately 1/10 chance of winning each monthly sweepstakes for a month in which you attended a follow-up appointment.
- ☐ All participants who successfully complete their follow-up appointments and meet the conditions will be entered into the sweepstakes. Sweepstakes winners will be selected using a computer random number generator.

## **OTHER INFORMATION**

We may end your participation for a number of reasons: 1) during the course of the survey, interview, or counseling sessions, it becomes clear that you do not meet study eligibility criteria, 2) if physical or psychological problems arise which would interfere with your participation in the study, 3) if we feel that it is in the best interests of your health or psychological well-being, or 4) if we believe that you are providing

inaccurate or false information. If we do dismiss you from the study, you will still receive partial compensation for the parts you have completed.

If you have any questions about the research study or experience a negative reaction that might have been caused by being in this study, please call Dr. John Pachankis immediately at 203-785-3710, write to him, or visit our research office in New York: ESTEEM, 220 E. 23<sup>rd</sup> St. Suite 405, New York, NY, 10010; or Miami: 1120 NW 14th St. 7th floor, Miami, FL 33136

You have rights as a research volunteer. Taking part in this study is voluntary. If you do not take part, you will neither incur a penalty nor lose benefits. You may stop participating in the study at any point, but will only receive compensation for the parts that you have completed. Ending your participation in this study or choosing not to participate is completely voluntary and will not affect benefits that you are otherwise entitled to.

The alternative to participation in this study is not to participate.

You should contact the Yale University Human Research Protection Program at (203) 785-4688 or the University of Miami Human Subject Research Office (HSRO) Office at 305-243-6713 if you have questions about your rights as a research participant or to discuss research-related injuries.

#### INFORMED CONSENT SIGNATURE PAGE

**The following is a list key information pieces you have received about this research study. If you have any questions about any of these items, please ask the person who is discussing the study with you for more information before agreeing to participate. Please verify you understand the following items:**

- ☐ What the study is about.
- ☐ What I must do when I am in the study.
- ☐ The possible risks and benefits to me.
- ☐ Who to contact if I have questions or if there is a research related injury.
- ☐ Any costs and payments.
- ☐ I can discontinue participating in the study at any time without penalty.
- ☐ Other choices.
- ☐ All written and published information will be reported as group data with no reference to my name.
- ☐ I have been given the name of the researcher and others to contact.
- ☐ I have the right to ask any questions.

_____ Printed Name of Participant	_____ Signature of Participant	_____ Date
_____ Printed Name of Person conducting the Informed Consent Process	_____ Signature of Person conducting the Informed Consent Process	_____ Date



## Appendix G

### Online & In-Person Screener - ESTEEM

In collaboration with researchers at the University of Miami and Columbia University, we are conducting a research study testing the effect of a mental health treatment designed by and for the gay community.

Do you want to complete this 5-minute survey to see if you are eligible for our study?

- Yes
- No

[Informed consent for online screener]

- Are you currently receiving regular mental health services from a psychologist, mental health counselor, social worker, or as part of a research study?
  - Yes
  - No
- If yes: How often are you receiving regular mental health services?
  - Once a week
  - Two to three times per week
  - Once a month
  - Every few months
  - A few times per year
- Please tell us your age.
- What is your current gender identity? (Select all that apply)
  - Man
  - Woman
  - Transgender Man (FTM)
  - Transgender Woman (MTF)
  - Gender Queer
  - Gender Non-Conforming (GNC)
  - Two-Spirit
  - Hijra
  - Other (please specify)
- How would you classify your sexual identity?
  - Gay
  - Bisexual
  - Heterosexual
  - Other (please specify)
- Are you planning on living in New York City/Miami for at least the next year?

- Have you used alcohol during the past 90 days?

**Please indicate how much you have been feeling any of the following ways over the last three months (last 90 days). From 0 for “Not at all” to 4 for “Extremely.”**

- Nervousness or shakiness inside
- Feeling tense or keyed up
- Feeling blue
- Feelings of worthlessness

\*\*\*Participants must have a mean of 2.5 for either the two depression items or two anxiety items. This is the same as the pilot, except for the R01, participants must also meet diagnostic criteria for depression, anxiety, or stress with the MINI.\*\*\*

**For the next three questions, main sexual partner refers to someone to whom you feel committed above anyone else and with whom you have had a sexual relationship. A casual partner refers to anyone else with whom you have a sexual relationship.**

- In the last 90 days, how many times have you had anal intercourse without a condom with a casual male partner?  
a. 0 times      b. once      c. twice or more      d. I don't know



- 14a. (*If > 0*) Are these casual male partners regularly taking PrEP?
- a. Yes
  - b. No
  - c. I don't know

- 14b. (*If > 0*) Are these casual male partners HIV-negative?
- a. Yes
  - b. No
  - c. I don't know

- 14c. (*If 14b = Yes*) How do you know?
- a. The participant knows that the partners are HIV-negative.
  - b. The participant does not know that the partners are HIV-negative.

- In the last 90 days, how many times have you had anal sex without a condom with a HIV-positive male partner?  
a. 0 times      b. once      c. twice or more      d. I don't know



- (*If > 0*) Was this HIV-positive male partner a main partner or a casual partner?
- Main partner
  - Casual partner
  - It happened with both a main partner and a casual partner

(If “*Main partner*”) Does this HIV-positive male partner have an undetectable viral load?

- a. Yes
- b. No
- c. I don’t know

- In the last 90 days, how many times have you had anal sex without a condom with a male partner (casual or main) whose HIV status you did not know?

- a. 0 times      b. once      c. twice or more      d. I don’t know

- Are you currently taking PrEP?

- ☐ Yes
- ☐ No

- (If yes) How many days per week do you take PrEP?

- ☐ 0
- ☐ 1
- ☐ 2
- ☐ 3
- ☐ 4
- ☐ 5
- ☐ 6
- ☐ 7

**In-person screener only:**

- Would you want to be contacted about future studies for which you might be eligible?

- ☐ Yes
- ☐ No

- If you are not eligible for the study, would you like us to delete your contact information from our database?

- ☐ Yes
- ☐ No

Phone Screening  
(Pachankis & Ivardic, 2016)

**Date:**    /    /   

**Screening ID Number:** \_\_\_\_\_

Hi, my name is \_\_\_\_\_. I am calling from the ESTEEM project at the Yale School of Public Health to follow-up with you about participating in one of our paid studies. In collaboration with researchers at the University of Miami and Columbia University, we are conducting a research study testing the effect of a mental health treatment designed by and for the gay community.

Do you want to complete this 15-minute survey to see if you are eligible for our study?

[If yes, proceed.]

[If no, thank the participant for his time and say, “Our website lists helpful resources for learning more about HIV risk and safer sex and also includes a list of community referrals for mental health, substance use, and sexual health counseling. You’ll find this information at WEBSITE under the “community resources” tab.]

Before we begin, do you currently have a working, private telephone number that we can use to get in touch with you in order to schedule and reschedule appointments?

[Participant’s contact information stored in separate, password-protected database]

### **Screener Questions**

Our team on the ESTEEM project includes LGBT-affirmative researchers who are interested in improving the health and wellbeing of the LGBT community. In collaboration with researchers from Yale University, University of Miami and Columbia University, we are conducting an investigational trial of different types of psychotherapy for gay and bisexual men who experience symptoms of anxiety and depression. The types of psychotherapy that we’re investigating in this trial involve meeting over the course of 10 one-hour sessions with a trained, gay-affirmative therapist. But some participants will not receive any psychotherapy.

If it seems like you are eligible after answering these questions today, we'll ask you to come in for two appointments over the next two weeks or so that will each last about two hours. At these first two appointments, you will complete an interview asking questions about your experiences being gay or bisexual, your mental health, and your sexual health-related behavior. During the first appointment, you will take an HIV test and tests for other sexually transmitted infections. The HIV test is a rapid test and you will get results in about 20-30 minutes. Your STI results will return in about a week. If you're HIV-negative, a computer will randomly assign you to receive 10 sessions of therapy in our office, receive therapy at the office of a community mental health center,

or receive a brief discussion about sexual risk. If you are randomly assigned to receive therapy, you will receive 10 weekly therapy sessions. Regardless of whether you receive therapy, you will complete a total of five appointments where you'll complete an interview in our office. At the last of these appointments, we'll give you another rapid HIV test and give you your results. You will earn \$25 for each of the first two visits. If you are randomly selected to receive the therapy, you will receive \$10 for completing each therapy session. Also, you will receive \$50 for completing each of three follow-up visits. So in total, you could receive up to \$300 over the course of about one year for participating in this study.

Do you have any questions?

Please remember you can stop this pre-screening at any point and/or skip any questions. All of the information you provide us is strictly confidential to the extent permitted by law. This means that your answers are not linked or connected in any way to your name or contact information. We may use the information we collect for research activities related to this study or to look at recruitment trends.

- After hearing about the study, are you still interested in answering some questions to see if you're eligible?
  - Yes
  - No

#### Demographic Questions

(Created for this study by Pachankis & Ivardic, 2016)

- How did you hear about this study?
- Are you comfortable completing study tasks in English, including reading and verbally responding to questions about mental health and sexual health in English?
  - a. Yes
  - b. No
- In the past 12 months, have you received regular mental health services from a psychologist, mental health counselor, social worker, or as part of a research study? \*
  - Yes
  - No
- In the past 12 months, have you received cognitive behavioral therapy, or CBT? CBT means types of treatment where you learn skills to challenge your thinking, face difficult situations to push you out of your comfort zone, or try new behaviors to get out of unhealthy habits. \*
  - Yes
  - No

- How often have you received CBT? \*
  - 1-4 times
  - 5-7 times
  - 8 or more times
- How often are you receiving regular mental health services? \*
  - a. Once a week
  - b. Two or three times per week
  - c. Once a month
  - d. Every few months
  - e. A few times per year

\* Note: to be eligible, participants must not be receiving regular mental health services on an ongoing basis (e.g., more than once per month) and cannot have received 8 or more sessions of CBT within the past 12 months.

- Please tell me your age:
- What is your current gender identity? (Select all that apply)
  - Man
  - Woman
  - Transgender Man (FTM)
  - Transgender Woman (MTF)
  - Gender Queer
  - Gender Non-Conforming (GNC)
  - Two-Spirit
  - Hijra
  - Other (please specify)
- What best describes your sexual identity?
  - gay
  - bisexual, but mostly gay
  - bisexual, equally gay and heterosexual
  - bisexual, but mostly heterosexual
  - heterosexual
  - queer
  - uncertain, don't know for sure
- Do you consider yourself Hispanic or Latino?
  - Yes
  - No
- What racial or ethnic group do you belong to?
  - American Indian or Alaska Native
  - Asian

- Black/African American
- Native Hawaiian or Other Pacific Islander
- White
- Multiracial
- Other (please specify)
- What is your HIV Status?
  - Negative
  - Positive
  - Unknown
- What city do you live in? State? ZIP code? Borough (if in NYC)?
- Are you planning on living in NYC/Miami for at least the next year?
  - Yes
  - No
- Are you currently participating in any other studies?
  - Yes
    - If yes, can you tell me the name of the study you are currently participating in? If you do not remember, can you tell me a little bit about what you do in the study?
  - No
- Have you used alcohol during the past 90 days?
  - a. Yes
  - b. No

Abbreviated Brief Symptom Inventory  
(Lang, Norman, Means-Christensen, & Stein, 2009):

**Please indicate how much you have been feeling any of the following ways over the last three months (last 90 days). From 0 for “Not at all” to 4 for “Extremely.”**

- Nervousness or shakiness inside
- Feeling tense or keyed up
- Feeling blue
- Feelings of worthlessness

\*\*\*Participants must have a mean of 2.5 for either the two depression items or two anxiety items. This is the same as the pilot, except for the R01, participants must also meet diagnostic criteria for depression, anxiety, or stress with the MINI.\*\*\*

Past 3-month Pre-exposure Prophylaxis (PrEP) Use  
(Created for this study by Eldahan, 2016)

**Pre-exposure prophylaxis, or PrEP, is a way for people who do not have HIV but who are at substantial risk of getting it to *prevent* HIV infection by taking a pill every day. The pill (brand name Truvada) contains two medicines used to treat HIV. When someone is exposed to HIV through sex for example, these medicines can work to keep the virus from establishing a permanent infection.**

- Have you ever taken PrEP (pre-exposure prophylaxis) to reduce the likelihood of getting HIV?
  - Yes, I am *currently* taking HIV PrEP
  - I am *not currently* taking HIV PrEP, but *I have taken PrEP within the past 3 months* (since \_\_\_\_\_)
  - I am *not currently* taking HIV PrEP, but *I have taken PrEP more than 3 months ago*
  - No, I have *never* taken HIV PrEP

IF “Yes, I am currently taking HIV PrEP.”

- About how often do you take PrEP?
  - About 1-2 times per week
  - About 3 times per week
  - About 4 times per week
  - About 5-6 times per week
  - 7 times per week
  - I don’t take PrEP regularly enough to know

[Participants are **NOT** only eligible if they have PrEP adherence of 4+ times per week.]

#### HIV Risk

(Created for this study by Ivardic, Mitchel, Pachankis, 2015)

**For the next three questions, main sexual partner refers to someone to whom you feel committed above anyone else and with whom you have had a sexual relationship. A casual partner refers to anyone else with whom you have a sexual relationship.**

- In the last 90 days, how many times have you had anal intercourse without a condom with a casual male partner?
  - a. 0 times
  - b. once
  - c. twice or more
  - d. I don’t know



14a. (*If > 0*) Are these casual male partners regularly taking PrEP?

- a. Yes
- b. No
- c. I don’t know

14b. (*If > 0*) Are these casual male partners HIV-negative?

- a. Yes



- b. No
- c. I don't know

14c. (If 14b = Yes) How do you know?

- c. The participant knows that the partners are HIV-negative.
- d. The participant does not know that the partners are HIV-negative.

- In the last 90 days, how many times have you had anal sex without a condom with a HIV-positive male partner?

- a. 0 times      b. once      c. twice or more      d. I don't know



(If > 0) Was this HIV-positive male partner a main partner or a casual partner?

- Main partner
- Casual partner
- It happened with both a main partner and a casual partner

15b. (If “Main partner”) Does this HIV-positive male partner have an undetectable viral load?

- a. Yes
- b. No
- c. I don't know

- In the last 90 days, how many times have you had anal sex without a condom with a male partner (casual or main) whose HIV status you did not know?

- a. 0 times      b. once      c. twice or more      d. I don't know

- (If the participant endorses sexual risk) Just to confirm, in the last 90 days, have you had sex without a condom with someone whose HIV status you did not know for sure or who is HIV-positive, when neither of you were on PrEP?

- a. Yes
- b. No

### Eligible

- It looks like you might be eligible for the study. Are you still interested in participating?



- a. Yes
- b. No (See **Decline**)

Thanks. Now let's schedule your first appointment. Where do you live? (recorded in Contact Database) Also, for our records, what's your date of birth? (recorded in Contact Database)

If eligible, obtain the address\_\_\_\_\_

Thank you for being willing to help us with our study. Do you have a pen handy because I would like to give you our address and your appointment time? You are schedule for an appointment:

On: \_\_\_\_\_

At: \_\_\_\_\_

With: \_\_\_\_\_

I just wanted to remind you of a few things to make your appointment go as easily as possible:

- We've booked this time in our schedule for you. I'll be sure that [study staff conducting appointment] will be here as well. We'll be waiting here for you, so if you are running more than 15 minutes late for your appointment, please just let us know ahead of time. If you can't make the appointment, please give us a call as far in advance as possible so we can arrange the schedule accordingly.
- I'd like to remind you again that all of the information that you provide us with is confidential to the extent permitted by law.
- We will be doing HIV and STI testing at this appointment. The STI tests will involve giving a urine sample and an oral and rectal swab. You will get your HIV test results at the end of your visit and your STI tests results in about a week.
- Also, please be advised that we cannot conduct the interview if you are under the influence of alcohol or drugs. If you show up for your appointment under the influence, we will have to reschedule your appointment.
- Our address is: [220 E 23<sup>rd</sup> St., Suite 405, New York, NY] [1120 NW 14<sup>th</sup> St., Suite 787, Miami, FL 33136]. Our phone number is: (New York – 646-344-4060) (Miami - 305-243-3508).

Thank you for your time today!

### **Not Eligible**

Thank you for taking the time to talk with me today. Unfortunately, it looks like you are not eligible for the study. As this is a new study, the eligibility criteria may change at some point.

- Would you like for us to contact you in that case?

a. Yes

b. No



In order to contact you about future studies, we would like to retain your name and contact information in our database. Is it okay if we keep your name and contact information in our database?

a. Yes

b. No

Our website lists helpful resources for learning more about HIV risk and safer sex and also includes a list of community referrals for mental health, substance use, and sexual

health counseling. You'll find this information at WEBSITE under the "community resources" tab.

**Decline**

Thank you for taking the time to talk with me today.

- You don't have to the next question if you do not wish, but it would be useful for us to know why you decided not to participate.
  - a. Not interested in study topic
  - b. Study topic too sensitive/personal
  - c. Scheduling difficulties
  - d. Concerned about confidentiality
  - e. Other (*specify*)
- Would you like us to contact you in the future about other studies for which you might be eligible for?
  - a. Yes
  - b. No
- In order to contact you about future studies, we would like to retain your name and contact information in our database. Is it okay if we keep your name and contact information in our database?
  - a. Yes
  - b. No



Our website lists helpful resources for learning more about HIV risk and safer sex and also includes a list of community referrals for mental health, substance use, and sexual health counseling. You'll find this information at WEBSITE under the "community resources" tab.

[illegible]

## Results

The total number of subjects required: 152 (76 in each group)

Test family	t-test
Sample groups	Independent groups
Number of tails	Two
Effect size	0.46
Significance level ( $\alpha$ )	0.05
Power	0.8
	Submit

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